(54) Title: SYSTEMS AND METHODS FOR ABLATING BODY TISSUE USING PREDICTED MAXIMUM TISSUE TEMPERATURE
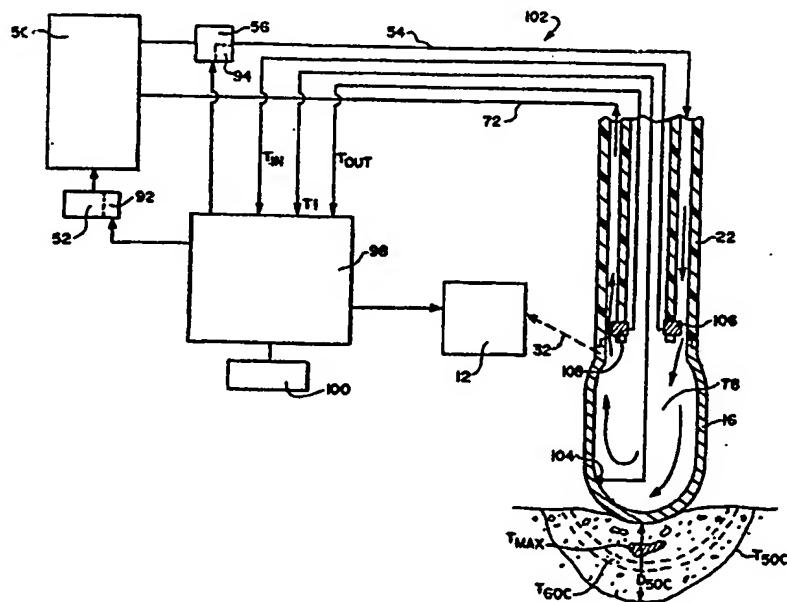
(57) Abstract

This invention is systems and methods that ablate body tissue using an electrode (16) for contacting tissue at a tissue electrode interface to transmit ablation energy at a determinable power level. The systems and methods include an element (50) to remove heat from the electrode (16) at a determinable rate. The systems and methods employ a processing element (98) to derive a prediction of the maximum tissue temperature condition occurring beneath the tissue electrode interface. The processing element (98) controls the power level of ablation energy transmitted by the electrode (16), or the rate at which the electrode (16) is cooled, or both, based, at least in part, upon the maximum tissue temperature prediction.

SYSTEMS AND METHODS FOR ABLATING BODY TISSUE
USING PREDICTED MAXIMUM TISSUE TEMPERATURE

Field of the Invention

5   In a general sense, the invention is directed to systems and methods for creating lesions in the interior regions of the human body. In a more particular sense, the invention is directed to systems and methods for ablating heart tissue for treating cardiac conditions.

10   ### Background of the Invention

Physicians frequently make use of catheters today in medical procedures to gain access into interior regions of the body. In some procedures, the catheter carries an energy transmitting element

15   on its distal tip to ablate body tissues.

In such procedures, the physician must establish stable and uniform contact between the energy transmitting element and the tissue to be ablated. Upon establishing contact, the physician

20   must then carefully apply ablating energy to the element for transmission to the tissue.

The need for precise control over the emission of ablating energy is especially critical during catheter-based procedures for ablating heart

25   tissue. These procedures, called electrophysiology

therapy, are becoming increasingly more widespread for treating cardiac rhythm disturbances, called arrhythmias. Cardiac ablation procedures typically use radio frequency (RF) energy to form a lesion in
5   heart tissue.

The principal objective of the invention is to provide systems and methods for monitoring and reliably controlling the application of energy to ablate body tissue, thereby providing therapeutic
10   results in a consistent and predictable fashion.

Summary of the Invention

The invention provides systems and methods that provide reliable control over tissue heating and ablation procedures.

15   .   The invention provides systems and methods for ablating body tissue using an electrode for contacting tissue at a tissue-electrode interface to transmit ablation energy at a determinable power level. The systems and methods include an element
20   to remove heat from the electrode at a determinable rate. The systems and methods employ a processing element to derive a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface.

25   In a preferred embodiment, the processing element generates an output based upon the maximum tissue temperature prediction.   In   one implementation, the processing element controls the power level of ablation energy transmitted by the
30   electrode based, at least in part, upon the maximum tissue temperature prediction.   In   another implementation, the processing element controls the rate at which heat is removed from the electrode based, at least in part, upon the maximum tissue
35   temperature prediction.

In a preferred embodiment, the processing element samples the power level at which the electrode transmits ablation energy and the temperature of the electrode to derive the maximum tissue temperature prediction.

In another preferred embodiment, the processing element samples the power level at which the electrode transmits ablation energy , the temperature of the electrode, and the rate at which heat is removed from the electrode to derive the maximum tissue temperature.

In another preferred embodiment, the processing element retains a function that correlates an observed relationship among maximum tissue temperature below the tissue-electrode interface and a set of predetermined operating conditions. In this embodiment, the processing element samples an actual operating condition and compares the actual operating condition to the function. The processing element derives from the comparison the prediction of the maximum tissue temperature.

Other features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended claims.

Brief Description of the Drawings

Fig. 1A is a system for ablating tissue using an actively cooled ablation electrode and associated cooling medium delivery system that embodies the features of the invention;

Fig. 1B is a diagrammatic view of a lesion profile, without an actively cooled ablation electrode;

Fig. 1C is a diagrammatic view of a lesion

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profile, with an actively cooled ablation electrode;

Fig. 1D is a graph showing the increase in lesion volume as a function of the cooling temperature of the ablation electrode;

5   Fig. 2A is a side section view of an actively cooled electrode of the open system variety that can be used in the system shown in Fig. 1A;

Fig. 2B is a section view of the end of the actively cooled electrode shown in Fig. 2A ;

10   Fig. 3A is a side section view of another actively cooled electrode of the open system variety that can be used in the system shown in Fig. 1A;

Fig. 3B is a section view of the end of the actively cooled electrode shown in Fig. 3A taken

15   generally along line 3B-3B in Fig. 3A;

Fig. 4 is a diagrammatic view of an actively cooled electrode like that shown in Fig. 3A in contact with tissue and with different types of medium being conveyed out of the cooling lumens;

20   Fig. 5 is a side section view of another actively cooled electrode of the open system variety that can be used in the system shown in Fig. 1A;

Fig. 6 is a side section view of an actively cooled electrode of the closed system

25   variety that can be used in the system shown in Fig. 1A;

Fig. 7 is a side section view of an electrode actively cooled using a Peltier diode that can be used in the system shown in Fig. 1A;

30   Fig. 8 is a diagrammatic view of a system for establishing a desired temperature boundary condition between an ablation electrode and endocardial tissue by actively cooling the electrode at a controlled rate;

35   Fig. 9A is a diagrammatic view of a system

that adjusts the level of RF power delivered to a cooled electrode based upon the sensed electrode temperature and the rate that ablation power is conveyed into the tissue through the cooled electrode;

Fig. 9B is a diagrammatic view of a neural network that can be used in association with the system shown in Fig. 9A;

Fig. 10 is a side section view of an actively cooled energy transmitting electrode that can be associated with the system shown in Fig. 1A, showing an outward projecting, blunt end temperature sensing element carried within a heat conducting cap by the electrode for sensing tissue temperature below the tissue surface;

Fig. 11 is an exploded side view of the temperature sensing element shown in Fig. 10;

Fig. 12 is a side section view of an actively cooled energy transmitting electrode that can be associated with the system shown in Fig. 1A, showing an outward projecting, pointed end temperature sensing element carried within a heat conducting cap by the electrode for sensing tissue temperature below the tissue surface;

Fig. 13 is a side section view of an actively cooled energy transmitting electrode that can be associated with the system shown in Fig. 1A, showing a movable temperature sensing element carried within a heat conducting cap by the electrode, the sensing element being shown in its retracted position within the electrode;

Fig. 14 is a side section view of the energy transmitting electrode shown in Fig. 13, showing the movable temperature sensing element in its extended position projecting into tissue;

Fig. 15A is a section view of the manually rotatable stylet used to adjust the position of the movable temperature sensing element shown in Figs. 13 and 14;

Fig. 15B is an enlarged view of an actively cooled electrode with an externally threaded, movable temperature sensing element;

Fig. 15C is an enlarged view of an actively cooled electrode with a cork screw-type carrier for the temperature sensing element;

Fig. 16 is a section view of an alternative manual, push-pull type stylet used to adjust the position of the movable temperature sensing element;

Fig. 17A is an enlarged end view of an actively cooled energy transmitting electrode carrying an outward projecting temperature sensing element with multiple temperature sensors for sensing multiple sub-surface tissue temperatures;

Fig. 17B is an enlarged end view of an actively cooled electrode carrying a temperature sensing element that projects into tissue having multiple temperature sensors associated with spaced regions of thermal conductive material substantially isolated from thermal conductive contact with each other;

Fig. 18 is an enlarged end view of an actively cooled energy transmitting electrode carrying multiple temperature sensing elements, each sensing element projecting into tissue to sense sub-surface tissue temperature;

Fig. 19 is a diagrammatic view of a system that adjusts the level of RF power delivered to a cooled electrode based in part upon actual maximum sub-surface tissue temperatures sensed by a temperature sensing element that penetrates below

the tissue surface;

Fig. 20 is a section view of a motor driven stylet used to adjust the position of the movable temperature sensing element shown in Figs. 13 and 14, with an associated feedback controller that seeks the region of highest sub-surface tissue temperature;

Fig. 21 is a diagrammatic view of an apparatus for acquiring experimental data to create a function that correlates a relationship among lesion boundary depth, ablation power level, ablation time, maximum tissue temperature, and electrode temperature that can be used by a processing element to control an ablation procedure to target lesion characteristics; and

Fig. 22 is a diagrammatic flow chart showing a process that the feedback controller for the motor driven stylet shown in Fig. 20 can use to position the temperature sensor in the region of highest sub-surface tissue temperature.

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

Description of the Preferred Embodiments

Fig. 1A shows a system 10 for ablating human tissue that embodies the features of the invention.

In the illustrated and preferred embodiment, the system 10 includes a generator 12 that delivers radio frequency energy to ablate

22, and a catheter distal section 24, which carries the electrode 16.

The handle 20 encloses a steering mechanism 26 for the catheter tip 24. A cable 28 extending from the rear of the handle 20 has plugs 30. Some of the plugs 30 are coupled to a signal wire 32 (see Fig. 2A) that extends from the ablation electrode 16 through the catheter body 22. The plugs 30 connect to the generator 12 for conveying radio frequency energy to the ablation electrode 16 through the wire 32.

Left and right steering wires 34 (also see Fig. 2A) extend through the catheter body 22 to interconnect the steering mechanism 26 in the handle 20 to the left and right sides of a deflecting spring element 36. Rotating a steering lever 38 on the handle to the left causes the steering mechanism 26 to pull on the left steering wire, causing the spring element 36 to bend to the left (as shown in phantom lines in Fig. 1A). Similarly, rotating the steering lever 38 to the right causes the steering mechanism 26 to pull on the right steering wire 34, causing the spring element 36 to bend to the right (as also shown in phantom lines in Fig. 1A). In this way, the physician steers the ablation electrode 16 into contact with the tissue to be ablated.

Further details of this and other types of steering mechanisms for the ablating element 10 are shown in Lunquist and Thompson U.S. Patent 5,254,088, which is incorporated into this Specification by reference.

A. **Actively Cooled Electrodes**

In the illustrated and preferred embodiment, the system 10 includes an assembly 40 for actively

cooling the electrode 16. Cooling forces the electrode-tissue interface to lower temperature values, As a result (as Figs. 1B and 1C show), the hottest iso-thermal region T_{MAX} is shifted deeper

5   into the tissue. This, in turn, shifts the 50° C iso-thermal region (designated T_{50C}), which determines the boundary of the tissue rendered nonviable by ablation, deeper into the tissue. An electrode that is actively cooled can be used to

10   transmit more ablation energy into the tissue, compared to the same electrode that is not actively cooled. As a comparison of Figs. 1B and 1C shows, the net result is that, with cooling, the lesion (designated L1 and L2, respectively, in Figs. 1B and

15   1C) extends deeper into the tissue and has a larger volume.

      Fig. 1D shows this effect graphically. Assuming a maximum tissue temperature T_{MAX} of about 94° C, actively cooling the electrode to an electrode

20   temperature T1 below about 35° C leads to at least a 50% increase in lesion volume. At an electrode temperature T1 below about 25° C, lesion volumes increase by about 100%, i.e., lesion volumes double in size.

25   There are various ways to structurally provide an electrode that can be actively cooled during use.

1.   Open Loop Cooling

      In the embodiment shown in Figs. 2A and 2B, the catheter body 22 includes an interior lumen 42. The

30   proximal end of the lumen communicates with a connection port 44 in the handle (see Figs. 1A and 15A). The distal end of the lumen 42 communicates with a hollow cavity 46 formed in the electrode 16.

      In the illustrated and preferred embodiment, the

35   cavity 46 includes an array of outlet apertures 48

clustered at the distal tip of the electrode 16.
Alternatively, a single centrally located outlet
aperture, or other arrangements of one or more
apertures, could be provided in the distal tip of
5   the electrode 16.

In this arrangement, the cooling assembly 40
includes a source 50 (see Fig. 1A also) of a
biocompatible medium, such as saline, with or
without heparin. A mechanism 52 cools the medium
10   source 50 to a desired temperature. A supply line
54 with an in-line pump 56 supplies the cooled
medium to the connection port 44 on the handle 20.
The cooled medium flows through the lumen 42 and
into the electrode cavity 46. The outlet apertures
15   48 discharge the cooled medium into the region
surrounding the electrode, as Fig. 2A shows. Because
the cooling medium is discharged directly into the
space surrounding the electrode 16, this arrangement
will be called "open" loop cooling.
20   The flow of cooling liquid through the electrode
cavity 46 conveys heat away from the thermal mass of
the electrode 16 by conductive and convective
cooling. The system further includes a controller 58
(see Fig. 1A) for controlling the rate of cooling,
25   as will be described in greater detail later.

Preferably, the flow of media through the outlet
apertures 48 is sufficient to sustain a positive
fluid pressure throughout use, thereby preventing
clotting about the electrode 16. The size and
30   number of outlet apertures 48 determine the
magnitude of the flow resistance through the
electrode 16..

The orientation of the outlet apertures 48 also
affects the efficiency of the cooling effect.
35   Preferably, the outlet apertures 48 are clustered at

the distal end of the electrode 16, as Figs. 2A and 2B show. This orientation directs the cooling medium through the entire length of the electrode 16 for better cooling effect. The discharged cooling medium also flows directly into and through the electrode-tissue interface, causing direct cooling of the tissue area being ablated. The direct cooling can reduce the incidence of charring.

Figs. 3A and 3B show an alternative structural embodiment of an actively cooled electrode of an "open" loop type. In this embodiment, an exterior sleeve 60 surrounds the catheter body 22, forming a circumferential space. The space is compart-mentalized by dividers 62 (see Fig. 3B) into multiple, circumferentially spaced lumens 64. Of course, the number of lumens 64 can vary.

The proximal end of the sleeve 60 communicates with the connection port 44 on the handle 20. The lumens 64 simultaneously conduct cooling medium supplied to the connection port 44 by the source 50 via the supply line 54 and in-line pump 56. The distal end of the sleeve 60 opens along the exterior sidewall of the electrode 16. There, the lumens 64 discharge the cooling medium along the periphery of the electrode 16 to cool it.

Alternatively, the sleeve 60 can be made to be moved axially along the catheter body 22 like an introducer sheath. In this arrangement, the position of the slidable sleeve can be adjusted to achieve optimal outflow of cooling medium about the electrode.

Optionally, as Fig. 4 shows, the multiple lumens 64 formed within the exterior sleeve 60 can conduct media having different characteristics benefiting the ablation process. For illustrative purposes,

Fig. 4 shows three lumens, designated 64A, 64B, and 64C. The lumen 64A adjacent the region of the electrode 16 in most intimate contact with tissue conducts a hypertonic liquid A having a relatively

5   low resistivity at, for example, about 15 ohm·cm, compared to resistivity of blood, which is about 150 ohm·cm. The hypertonic liquid A discharged in this region therefore improves the transmission of RF energy from the electrode 16 into the tissue,

10   regardless of whether or not the electrode 16 is also actually cooled by the liquid in the process. The other lumens 64B and 64C adjacent the region of the electrode 16 exposed to the blood pool can conduct another liquid B having a relatively high

15   resistivity, compared to blood, of, for example, about 1500 ohm·cm. The liquid B could comprise, for example, a 5% dextrose solution. The liquid B therefore reduces the transmission of RF energy from the electrode 16 into the blood pool, again

20   regardless of whether liquid B also cools the electrode 16 in the process. Furthermore, heparin could be supplied with liquid A through the lumen 64A adjacent the tissue-contacting region of the electrode 16 to locally reduce the incidence of

25   clotting, while no heparin is supplied through the lumens 64B and 64C adjacent the blood-pool exposed region of the electrode 16. In this way, the volume of anticoagulant introduced into the blood pool can be more locally directed and controlled.

30   Fig. 5 shows another alternative embodiment of an actively cooled electrode of the "open" loop type. In this embodiment, the electrode 16 comprises a foam body 66 of an open cell porous material coated with an electrically conductive substance. The

35   electrically conductive substance can be coated on

the porous material 66 using, for example
conventional ion beam assisted deposition (IBAD), or
similar vapor deposition techniques.

Coated foam body 66 is molded to assume what can
5   be called a normal shape. In the illustrated em-
bodiment (as Fig. 5 shows), the normal uncompressed
shape is generally spherical. However, the original
uncompressed shape can be rectangular, square, oval,
toroid, or virtually any other shape. Due to its
10   porous, open structure, the body 66 can be
collapsed, without damage, by an external com-
pression force during deployment in a guide tube
(not shown) into another more compact shape.

As in the Figs. 2A/B embodiment, an interior
15   lumen 68 supplies cooling medium to the porous
material of the body 66 from an external source 50
(not shown in Fig. 5). The porous material of the
body 66 uniformly perfuses the cooling medium from
the lumen 68 for discharge at the surface of the
20   medium.

2. Closed Loop Cooling

Fig. 6 shows an embodiment of electrode 16 that
is actively cooled in a "closed" loop manner. During
"closed" loop cooling, the cooling medium is not
25   discharged outside the electrode 16 at the ablation
site. Instead, the cooling medium is circulated
back to the source 50 or to waste 70 away from the
ablation site.

In this arrangement, the system includes, in
30   addition to the previously described source 50,
supply line 54, and pump 56, a return line 72 that
conveys medium away from the electrode 16. The
catheter body 22 includes an interior supply lumen
74 and an interior discharge lumen 76. The proximal
35   ends of the lumens 74 and 76 communicate with the

connection port 44 on the handle 20, with the supply
lumen 74 in communication with the supply line 54
and the discharge lumen 76 in communication with the
return line 72.

5   The distal ends of the lumens 74 and 76
communicate with a hollow cavity 78 formed in the
electrode 16.   The supply line 54 supplies the
cooled medium through the supply lumen 74 into the
cavity 78, while the return line 72 returns the
10   medium through the discharge lumen 76 to the medium
source 50 or to waste 70. As before, the flow of
cooling liquid through the electrode cavity 78
conveys heat away from the thermal mass of the
electrode by conductive and convective cooling.

15   In a "closed" loop arrangement, a pressurized gas
could be used as the cooling medium.   The
pressurized gas would be allowed to expand within
the electrode chamber, cooling the electrode by the
Joule-Thompson effect. The use of a pressurized gas
20   and the Joule-Thompson effect to cool an electrode
is disclosed in Jackson et al. U.S. Patent No.
5,281,217, which is incorporated herein by
reference.

3.   Diode Cooling

25   In the alternative embodiment shown in Fig. 7,
the cooling assembly 40 includes a conventional
Peltier cooling diode 80 associated with the
electrode 16, which is also electrically coupled by
wire 32 to the generator 12. The materials of the
30   diode 80 are complex alloys, one doped "p" and the
other doped "n", like semiconductors, creating a
thermocouple at the junction. An applied voltage
potential passes current from a source 88 through
the junction. The polarity of the voltage creates
35   a "cold" side 82 of the diode 80, which is coupled in

thermal conductive contact to the electrode 16, and a "hot" side 84 of the diode 80, which is coupled in thermal conductive contact to a heat dispersing element 86. The dispersing element 86 can be carried on the catheter body 22 away from the electrode 16 and in contact with the blood pool.

The passage of current through the diode 80 creates a heat pump from cold side 82 to hot side 84, conducting heat energy from the thermal mass of the electrode 16 to the heat dispersing element 86. Heat energy can thus be transferred from the thermal mass of the electrode 16 to cool it.

Fig. 7 shows the Peltier diode 80 being used in place of a source 50 of cooling medium to actively cool the electrode 16 in either an open or closed loop fashion. It is believed that the heat transfer capabilities of conventional Peltier diodes 50, coupled with the normal convective cooling effects of the dispersing element 86 by the blood pool can accommodate the requirements for active cooling of most ablation electrodes 16. Alternatively, the Peltier diode 80 can be used in combination with a flowing source 50 of cooling medium to actively cool the electrode.

B.   Ablation Control Using Electrode Cooling

1.   Prescribing a Desired Lesion Depth

Fig. 8 diagrammatically shows a system 90 for establishing a desired temperature boundary condition between an ablation electrode 16 and endocardial tissue by actively cooling the electrode 16 at a controlled rate.

The system 90 includes the generator 12 of RF ablation energy electrically coupled by the wire 32

to the ablation electrode 16, which is deployed
within the body in contact with heart tissue. In
the illustrated embodiment, when used for cardiac
ablation, the generator 12 is typically conditioned
5   to deliver up to 150 watts of power at a radio fre-
quency of 500 kHz.

The system 90 shown in Fig. 8 also includes the
source 50 of medium for cooling the electrode, as
well as the mechanism 52 for cooling the medium. The
10   mechanism 52 includes a controller 92 for
establishing and maintaining a desired temperature
for the cooling medium in the source.

The supply line 54 and in-line pump 56 provide
communication between the source 50 and the
15   connection port 44 on the catheter handle 20.
Operation of the pump 56 conveys the cooled medium
to the electrode 16, as already described. Fig. 8
shows an open loop arrangement of the type shown in
Figs. 3A/B. A controller 94 coupled to the pump 56
20   establishes and maintains a commanded flow rate. In
a closed loop system, a return line 72 conveys the
medium from the electrode for return to the source
50 or to waste 70, in the manner shown in Fig. 6.

As shown in Fig. 8, the electrode 16 carries a
25   temperature sensor 96. The sensor 96 senses
instantaneous temperatures (T1) of the thermal mass
of the electrode 16. The temperature T1 at any
given time is a function of the power supplied to
the electrode 16 by the generator 12 and the rate at
30   which the electrode 16 is cooled by the medium.

The characteristic of a lesion can be expressed
in terms of the depth below the tissue surface of
the 50° C isothermal region T_{50C}, which marks the
boundary of tissue rendered nonviable. Fig. 8
35   designates this depth as D_{50C}. The depth D_{50C} is a

function of the physical characteristics of the ablation electrode (that is, its electrical and thermal conductivities and size); the angle between the tissue and the electrode; the temperature T1 of the thermal mass of the electrode; the magnitude of RF power (P) transmitted by the electrode into the tissue, and the time (t) the tissue is exposed to the RF power. These relationships can be observed empirically and/or by computer modeling under controlled real and simulated conditions, as the following Example will illustrate.

For a desired lesion depth $D_{50C,}$ additional considerations of safety constrain the selection of an optimal operating condition among the operating conditions listed in the matrix. The principal safety constraints are the maximum tissue temperature T_{MAX} and maximum power level P_{MAX}.

The maximum temperature condition T_{MAX} lies within a range of temperatures which are high enough to provide deep and wide lesions (typically between about 90° C and 98° C), but which are safely below about 100° C, at which tissue desiccation or tissue boiling is known to occur. It is recognized that T_{MAX} will occur a distance below the electrode-tissue interface between the interface and D_{50}.

The maximum power level P_{MAX} takes into account the physical characteristics of the electrode and the power generation capacity of the RF generator 12.

EXAMPLE (Determining a D_{50C} Function)

A 3-D finite element model is created for a cooled 8F diameter/5 mm long ablation electrode held generally perpendicular in contact with an approximately 4 cm thick rectangular slice of cardiac tissue. The tip of the electrode extends

about 1.3 mm into the tissue. The overall volume is a parallelpiped 8 cm long, 4 cm wide, and 4 cm thick. The model has 8144 nodes, using hexahedral elements and a nonuniform mesh.

5   The current density boundary conditions are set at the electrode, so that after 120 seconds (t) the maximum tissue temperature (T_{MAX}) reaches about 95° C. On the outer surface of the overall volume the potential is set to zero, and the temperature is 10   fixed at 37° C to account for the average body temperature. At the nodes on the electrode surface the temperature is set to a value that modeled the effects of actively cooling the electrode tip. This value (T1) is varied between 4° C and 50° C. The 15   finite element convective boundary condition at the electrode-blood interface is set to 1.8×10^{-5} Joule (J) per cubic millimeter (mm^3) second (s) Kelvin K ($J/mm^3 \cdot s \cdot K$).

          COSMOS is used on a Hewlett Packard workstation 20   to solve the electrical-thermal equations. The analysis looks at the effects of electrode cooling on lesion volume, on radio frequency power (P) required to keep T_{MAX} at about 95° C, and on the distance of the hottest tissue region beneath the 25   tissue-electrode interface. The lesion dimensions are estimated from the volume enclosed by the 50° C isothermal surface.

          The model results are corroborated with experimental data acquired using the apparatus shown 30   in Fig. 21. A 4 cm thick slice of bovine heart H is fixed in good contact with a 144 cm^2 patch electrode EP inside a tank T filled with saline at 37° C. An ablation catheter C carrying a cooled 8F diameter/5 mm long electrode E is placed in contact with the 35   tissue surface H at an angle of 90°. Water at about

4° C is circulated from a source CS inside the catheter. A 0.55 mm bead thermistor TM1 is placed at the electrode tip (to sense T1), and the sensed temperature (T1) is used as output to manually

5   control the cooled water flow rate (as shown by dotted lines in Fig. 21). The sensed temperature (T1) is kept constant at a predetermined value between 27° C and 40° C. A second thermistor TM2 is placed in the cardiac tissue H about 2 mm beneath

10   the electrode tip. The second thermistor TM2 placement corresponds to the hottest tissue temperature region predicted by the finite element simulations. The two thermistor readings are acquired at a sampling rate of 20 ms by LabView

15   running on a Power Mac IIci. A 500 kHz sinusoidal signal is applied between the ablation and indifferent electrodes using a 150 W RF ablation system AS. The delivered RF power (P) is kept constant at predetermined values between 6 watts (W)

20   and 20 W.

After the experiments are completed, the heart is removed from the tank, sliced transversely at each of the lesions, and the dimensions of the contours marking tissue discoloration are measured.

25   The bovine tissue used typically discolors at about 60° C, so the values obtained underestimate the dimension of *in vivo* lesions consisting of tissue heated above 50° C.

The following matrix sets forth the D_{50C} function

30   obtained using the above described methodology.

TABLE 1

D_{50c} Boundary Function

t = 120 seconds and T_{MAX} = 95° C

(For 8F 5 mm ablation electrode)

The master controller 98 is coupled to the RF generator 12, the temperature sensor 96, the cooling controller 92, and the pump controller 94. The master controller 98 includes in memory a matrix of operating conditions defining the D_{50C} temperature boundary function, as described above for t = 120 seconds and T_{MAX} = 95° C and for an array of other operating conditions.

The master controller 98 includes an input device 100. In the system 90 shown in Fig. 8, the physician uses the controller input device 100 to set a desired lesion depth in terms of D_{50C}. The physician also uses the input device 100 to identify the characteristics of the electrode, using a prescribed identification code; set a desired maximum RF power level P_{MAX}; a desired time t; and a desired maximum tissue temperature T_{MAX}.

For example, assume that the physician selects an 8F/5 mm ablation electrode. The physician also selects a desired therapeutic result in terms of a lesion depth D_{50C} = 9.2 mm. The physician further selects other details of the desired therapeutic result in terms of a targeted ablation time of t = 120 seconds; a maximum tissue temperature T_{MAX} = 95° C; and a maximum ablation power level P_{MAX} = 50 W.

Based upon these inputs, the master controller 98 compares the desired therapeutic result to the function defined in the matrix (as exemplified by the above Tables 1 and 2). The master controller 58 selects an operating condition to achieve the desired therapeutic result without exceeding the prescribed T_{MAX} by controlling the function variables.

In this example, based upon a desired T_{MAX} of 95° C and t = 120 seconds, the controller 98 commands

the generator 12 to maintain a fixed power level P
of 31 W (which does not exceed P_{MAX}) for the
prescribed time t = 120 seconds. The controller 98
simultaneously controls the rate at which the
5   electrode 16 is cooled (based upon Table 2) to
establish and maintain T1 at the level called for by
the function for the D_{50C} = 9.2 mm boundary selected,
which in this example is T1 = 30° C (flow rate = 9.3
ml/min).

10   The maximum tissue temperature will continuously
increase toward T_{MAX} during the targeted ablation
period t, with the rate of increase depending
principally upon the magnitude of P and T1. That
is, the rate of tissue temperature increase with be
15   greater at higher values of P and lower values of
T1, and vice versa.

The master controller 98 can control the cooling
rate in various ways. For example, the master
controller 98 can control the rate of cooling by
20   commanding the temperature controller 92 to adjust
the temperature of the cooling medium over time in
response to variations in T1 to establish and
maintain the set T1. Alternatively, the master
controller 98 can control the rate of cooling by
25   commanding the pump controller 94 to adjust the flow
rate of the cooling medium over time in response to
variations of T1 to establish and maintain the set
T1. The master controller 98 can also command the
controllers 92 and 94 in tandem to reach the same
30   result.

The manner in which the master controller 98
processes information pertaining to T1 to derive
control signals to vary medium temperature and
medium flow rate can vary. For example, the master
35   controller 98 can employ proportional control

principles, proportional integral derivative (PID)
control principles, adaptive control, neural
network, and fuzzy logic control principles.

When cooling is accomplished using the Peltier
5   cooling diode 80 (as Fig. 7 shows), the master
controller 98 establishes and maintains Tl by
commanding the current source 88 to adjust current
flow to the diode 80. When the diode 80 is used in
combination with active medium flow cooling (as Fig.
10 8 shows), the master controller 98 can set the
medium temperature and the medium flow rate in the
manners above described, and further control the
current source 88 to the diode to accomplish fine
adjustments to maintain the desired Tl.

15   It can be appreciated that various combinations
of cooling control using the diode 80 are also
possible. As before stated, the master controller
98 can employ proportional control principles,
proportional integral derivative (PID) control
20 principles, adaptive control, neural network, and
fuzzy logic control principles in varying the
current flow to the diode 80 based upon changes of
Tl over time.

At the end of the targeted ablation period t,
25 the controller 98 terminates power to the ablation
electrode. The desired lesion depth will be formed,
and T_{MAX} will not have exceeded the target of 95° C.

In alternative arrangements, the controller 98
can fix any one or more of the control variables Tl,
30 P, or t and vary the remaining one or more of the
control variables Tl, P, or t to achieve the desired
D_{50C} temperature boundary. The system 90 thereby
permits the physician, in effect, to "dial-a-lesion"
by specifying a desired D_{50C}. Using active cooling
35 in association with time and power control, the

controller 98 achieves the desired D_{50C} without the need to sense actual tissue temperature conditions.

3.   Predicting   Maximum   Tissue Temperature/Depth During Cooling

5   Fig. 9A shows a system 102 that adjusts the level of RF power delivered to a cooled electrode 16 and/or the cooling rate based upon a prediction of instantaneous maximum tissue temperature, which is designated T_{MAX} (t).

10   In a preferred implementation, the prediction of T_{MAX} is derived by a neural network, which samples at the current time (t) a prescribed number (k_n) of previous power levels P, previous rates at which heat has been removed to cool the electrode, and
15   previous electrode temperature.

The heat removal rate is identified by the expression $\mathring{A}$, where

$$A = c \times \Delta T \times RATE$$

where:

c is the heat capacity of the cooling
20   medium used (in Joules (J) per kilogram (kg) Kelvin (K), or J/kg K)

ΔT is the temperature drop in the cooling medium during passing through the electrode 16 (K), and

25   RATE is the mass flow rate of the cooling medium through the electrode (kg/sec).

The heat transmitted by the ablation electrode to the tissue is the difference between the heat generated by Joule effect and the heat removed by
30   active cooling. At a given temperature T1 and flow rate of cooling medium, the magnitude of $\mathring{A}$ increases as RF power delivered to the electrode 16 increases.

Together, T1 and Å represent an indirect measurement
of how rapidly the sub-surface tissue temperature is
changing.   Together, T1 and Å are therefore
predictive of the depth and magnitude of the hottest

5   sub-surface tissue temperature T_{MAX}, and thus
indirectly predictive of the lesion boundary depth
D_{50C}. Large deep lesions are predicted when T1 is
maintained at a low relative temperature (by
controlling cooling rate) and Å is maintained at a

10   high relative value (by controlling RF power).
Likewise, smaller lesions are predicted when T1 is
maintained at a high relative temperature and Å is
maintained at a low relative value.

The system 102 shown in Fig. 9A implements these

15   control criteria using an electrode 16 of a closed
system type, like that shown in Fig. 6.   The
electrode 16 carries three temperature sensing
elements 104, 106, and 108.   The first sensing
element 104 is in thermal contact with the thermal

20   mass of the electrode 16 to sense its temperature,
or T1 as already described.   The second sensing
element 106 is located to sense the temperature of
the cooling medium as it enters the electrode cavity
78, or T_{IN}. The third sensing element 108 is located

25   to sense the temperature of the cooling medium as it
exits the electrode cavity 78, or T_{OUT}.   In this
closed system arrangement, the temperature increase
in the cooling medium during its passage through the
electrode ΔT is computed as follows:

$$\Delta T = T_{OUT} - T_{IN} \qquad \qquad \text{Closed System}$$

30   In an open system arrangement (like that shown
in Figs. 2A/B and 3A/B), where the cooling medium is
discharged directly in the region of tissue in

contact with the electrode 16, there is no third
temperature sensing element 108. In this case, ΔT
is computed as follows:

$$\Delta T = T1 - T_{IN} \qquad\qquad \text{Open System}$$

In systems where environmental variables are
5   closely controlled, the prediction of T_{MAX} may be
derived from sampling at the current time (t) a
prescribed number (k_n) of previous power levels P and
previous electrode temperatures, without sampling Å.

In Fig. 9A, the master controller 98 is coupled
10   to the RF generator, the temperature sensing
elements 104, 106, and 108 (or 104 and 106 in an
open system), the cooling controller 92, and the
pump controller 94.

The controller 98 includes a neural network
15   predictor 144 (see Fig. 9B). The predictor 144 can
comprise a two-layer neural network, although more
hidden layers could be used.   The predictor 144
receives as inputs a first set of k_1 of weighted past
samples of Å, $\{Å\ (t-1)\ \text{to}\ (t-k_1)\}$; a second set of k_2
20   of weighted past samples of P, $\{P\ (t-1)\ \text{to}\ (t-k_2)\}$;
and a third set of k_3 samples of T1, $\{T1\ (t-1)\ \text{to}$
$(t-k_3)\}$. The number of samples in the sets $k_{1,2,3}$ can
be varied, according to the degree of accuracy
required. As an example, k_1 and k_2 are preferably in
25   the range of 5 to 20. k_3 can be selected equal to 1.

The predictor 144 can be variously configured.
In the illustrated embodiment, the predictor 144
comprises a two layer neural network, although more
hidden layers could be used.

30   In this implementation, the predictor 144
includes first and second hidden layers and four
neurons, designated $N_{(L,X)}$, where L identifies the

layer 1 or 2 and X identifies a neuron on that
layer. The first layer (L=1) has three neurons (X
= 1 to 3), as follows $N_{(1,1)}$; $N_{(1,2)}$; and $N_{(1,3)}$. The
second layer (L=2) comprising one output neuron

5   (X=1), designated $N_{(2,1)}$.

The weighted past samples {Å (t-1) to (t-k_1)}; {P
(t-1) to (t-k_2)}; and (in the alternative embodiment)
T1, {T1 (t-1) to (t-k_3)} are fed as inputs to each
neuron $N_{(1,1)}$; $N_{(1,2)}$; and $N_{(1,3)}$ of the first layer.

10 The output neuron $N_{(2,1)}$ of the second layer
receives as inputs the weighted outputs of the
neurons $N_{(1,1)}$; $N_{(1,2)}$; and $N_{(1,3)}$. Based upon these
weighted inputs, the output neuron $N_{(2,1)}$ outputs T_{MAX}
(t).

15 The predictor 144 must be trained on a known set
of data that have been previously acquired
experimentally. For example, using a back-
propagation model, the predictor 144 can be trained
to predict the known hottest temperature of the data

20 set with the least error. Once the training phase
is completed, the predictor 144 can be used to
predict T_{MAX} (t).

Alternatively, fuzzy logic or linear prediction
algorithms can be used to derive T_{MAX} (t) from

25 sampling past power P, electrode temperature T1, and
(in the preferred embodiment) cooling rate Å.

The master controller 98 receives from the
physician, via the input device 100, a desired
maximum tissue temperature value TT_{SET}, a desired

30 electrode temperature $T1_{SET}$, and a P_{MAX}.

The set temperature value TT_{SET} represents the
desired hottest sub-surface tissue temperature that
the physician wants to maintain at the ablation
site, consistent with the need to prevent micro-

35 explosions. The value TT_{SET} can comprise a fixed,

targeted magnitude, or the value of TT_{SET} can vary over time to define a set temperature curve, which can be either linear or nonlinear. Further details of using set temperature curves are disclosed in

5   U.S. Patent Application Serial No. 08/266,023, filed June 27, 1994, and entitled "Tissue Heating and Ablation Systems and Methods Using Time-Variable Set Point Temperature Curves for Monitoring and Control."

For $T1_{SET}$, the preferred embodiment takes into

10   account the relationship between electrode temperature T1 and increases in lesion volume shown in Fig. 1D, selecting as the desired $T1_{SET}$ a temperature below about 25° C and, most preferable, between about 10° C and about 25 C.

15   The value P_{MAX} is the highest allowed power level, based upon considerations already stated.

The master controller 98 periodically derives T_{MAX} (t) and compares T_{Max} (t) to TT_{SET} (t). Based upon this comparison, the master controller 98 derives a

20   demand power output, taking into account P_{MAX}, while cooling to maintain $T1_{SET}$. The demand power output represents the magnitude of the radio frequency power that should be supplied to the electrode 16 to establish and contain the desired maximum tissue

25   temperature TT_{SET} at a fixed value or along a set linear or nonlinear curve.

Alternatively, the master controller 98 could maintain a fixed power level below P_{MAX} and adjust the cooling rate Å based upon T_{MAX} (t) to contain TT_{SET}

30   at a fixed value or along a set curve. As before described, the master controller 98 can control the cooling rate by commanding the temperature controller 92 to adjust the temperature of the cooling medium over time, or by commanding the pump

35   controller 94 to adjust the flow rate of the cooling

medium over time, or by commanding the controllers
92 and 94 in tandem to reach the same result.

The manner in which the controller 98 derives
the control commands can vary. For example, it can
employ proportional control principles, proportional
integral derivative (PID) control principles,
adaptive control, neural network, and fuzzy logic
control principles. Further details of these control
principle are disclosed in copending U.S. Patent
Application Serial No. 08/266,023, filed June 27,
1994, and entitled "Tissue Heating and Ablation
Systems and Methods Using Time-Variable Set Point
Temperature Curves for Monitoring and Control."

Using active cooling in association with power
control and/or rate of energy removal at the
electrode, the controller 98 achieves the desired
rate of energy removal Å to achieve a desired lesion
characteristic. Like the system 90 shown in Fig. 8,
the system 102 shown in Fig. 9A achieves its lesion
formation objectives without the need to sense
actual tissue temperature conditions.

Alternatively, the master controller 98 can use
a matrix function to correlate observed operating
conditions, which Tables 1 and 2 exemplify in
partial form, to infer T_{MAX} without actually sensing
tissue temperature conditions.

In this implementation, the controller 98 senses
the flow rate of cooling media, the sensed electrode
temperature T1, and the power P. The controller 98
compares these sensed values to values set forth by
in matrix function. The controller 98 infers from
this comparison what T_{MAX} would be, according to the
function, under these sensed operating conditions.
The T_{MAX} inferred under this methodology becomes T_{MAX}
. For example, at a sensed cooling flow rate of 9.3

ml/min, a sensed power P of 31 W, and a sensed electrode temperature T1 of 30° C, Tables 1 and 2 would infer that T_{MAX} would be 95° C at an ablation time (t) of 120 seconds. In this implementation the inferred maximum tissue temperature becomes T_{MAX}. Power and/or cooling rate are then controlled to contain T_{MAX} at a fixed value or along a set curve.

3. Sensing Actual Maximum Tissue Temperature/Depth During Cooling

In the embodiments shown in Figs. 10 to 12, the cooled ablation electrode 16 carries at least one temperature sensing element 110 for sensing actual tissue temperature. In these embodiments, the power that the RF generator 12 applies to the electrode 16 is set, at least in part, by the actual tissue temperature conditions sensed by the element 110.

In the illustrated embodiment, the temperature sensing element 110 comprises a conventional small bead thermistor 112 with associated lead wires 114. In a preferred implementation, the thermistor 42 comprises a 0.55 mm bead thermistor commercially available from Thermometrics (Edison, New Jersey), Part Number AB6B2-GC16KA143E/37° C-A.

It should be appreciated that other types of temperature sensing elements can also be used. For example, a thermocouple could be used as the temperature sensing element. In a preferred implementation, the thermocouples are constructed by either spot welding or by laser stripping and welding the different metals together to form the thermocouple junction. When a thermocouple serves as the temperature sensing element, a reference thermocouple must be used. The reference thermocouple may be placed in the handle 20 or exposed to the blood pool in the manner disclosed in

copending U.S. Patent Application Serial No. 08/286,937, filed August 8, 1994, and entitled "Systems and Methods for Sensing Temperature Within the Body."

Potting compound 116 encapsulates the thermistor 112 and lead wires 114. The lead wires 114 are also enclosed in insulating sheaths 117, which electrically isolate the wires 114. Together, the compound 116 and sheaths 117 electrically insulate the thermistor 112 from the surrounding ablation electrode 16. For better performance, the wires should be electrically shielded.

The potting compound 116 and insulation sheaths 117 can be made with various materials. In the illustrated embodiment, heavy isomid serves as the potting compound 116, although another cyanoacrylate adhesive, a silicon rubber RTV adhesive, polyurethane, epoxy, or the like could be used. The sheaths 117 are made from polyimide material, although other conventional electrical insulating materials also can be used.

Similar electrical insulation is required when thermocouples are used as the temperature sensors. For example, the thermocouple junction can be placed in a thermally conducting epoxy inside a polyester sleeve. In a preferred implementation, the thermocouple junction is placed in silicon rubber RTV adhesive (NuSil Technologies, Carpenteria, California) within a shrink polyester sleeve, which is then shrunk to fit tightly about the thermocouple junction and wires. To reduce electrical interference, the thermocouple wires are also preferably shielded and twisted together.

The lead wires 114 for the thermistor 112 extend through the catheter body 22 and into the catheter

handle 20 (see Fig. 15A). There, the lead wires 114 electrically couple to the cable 28 extending from the handle 20. The cable 28 connects to the generator 12 and transmits the temperature signals
5   from the thermistor 112 to the generator 12.

In the embodiment illustrated in Figs. 10 to 12, the ablation electrode 16 includes an interior well 118 at its tip end. The temperature sensing element 110 occupies this well 118. The sensing element 110
10   shown in Figs. 10 to 12 extends beyond the tip of the electrode 16 to project beneath the surface of the endocardium. The sensing element 110 is thereby positioned to sense actual sub-surface tissue temperature conditions.

15   In the illustrated and preferred embodiment, the sub-surface temperature sensing element 110 is enclosed within a thermally conducting cap 120 (see Figs. 10 and 11). The cap 120 comprises a material having a high thermal conductivity that is at least
20   1.0 watt (W) per meter (m) Kelvin (K), or 1.0 W/m K. Metallic materials like stainless steel, gold, silver alloy, platinum, copper, nickel, titanium, aluminum, and compositions containing stainless steel, gold, silver, platinum, copper, nickel,
25   titanium, and aluminum possess this degree of thermal conductivity. For example, stainless steel has a thermal conductivity of about 15 W/m K, and platinum has a thermal conductivity of about 71 W/m K. This thermal conductivity is significantly
30   higher than the thermal conductivity of conventional polymer potting material surrounding the temperature sensor 110. For example, silicon rubber has a thermal conductivity of only about 0.13 W/m K, and polyurethane has a thermal conductivity of only
35   about 0.026 W/m K.

The cap 120 has an open interior 122. The encapsulated thermistor 112 snugly occupies the open cap interior 122 in thermal conductive contact with the thermal conducting material of the cap 120.

5   Preferably, the thermistor 112 is potted within the open interior 122 using an epoxy having an enhanced thermal conductivity that is at least 1.0 W/m K. The inclusion of a metallic paste (for example, containing aluminum oxide) in a standard epoxy

10   material will provide this enhanced thermal conductivity. When the ablation energy is radio frequency energy, the potting material must also electrically insulate the temperature sensing element 112 from the cap 120.

15   The cap 120 in turn is fitted within the well 118 of the electrode 16. The cap 120 has a distal end 124 that makes thermal conductive contact with the tissue. The high thermal conductivity of the cap material assures that the cap 120 will quickly

20   reach an equilibrium temperature close to that of the tissue it contacts.

In a representative preferred implementation (see Fig. 3), the cap 120 is made from stainless steel 304 (having a thermal conductivity of about 15

25   W/m K). The cap 120 has a wall thickness along the sidewall and at the distal end of about .005 inch. The cap 120 has an overall length of about .060 inch and an overall width of about .033 inch (the open interior being about .022 inch in width). The

30   encapsulated thermistor 42 is fixed to the cap interior 56 using a thermally conducting epoxy like EP42HTAO (Master Bond, Inc., Hackensack, New Jersey). The thermal conductivity of this epoxy (with aluminum oxide) is about 1.15 W/(m K).

35   The cap 120 provides enhanced thermal conducting

characteristics, creating an isothermal surface around the sub-surface sensing element 110 in thermal equilibrium with the surrounding tissue temperature conditions. The cap 120 also provides added strength to resist bending or fracture during manufacturing and handling.

In the illustrated and preferred embodiment, a thermal and electrically insulating barrier 142 forms an interface between the interior wall of the well 118 and the side of the cap 120 that occupies it. In a preferred embodiment, the barrier 142 comprises polyamide adhered about the sidewall of the cap 120 using FMD-14 to serve as an electrical insulator. The barrier 142 also comprises polyester shrink tubing secured by heat shrinking about the polyamide to serve as a thermal insulator.

In the illustrated and preferred embodiment, a thermal insulating tube 144 also lines the interior of the well 118 . The tube 144 further thermally insulates the temperature sensing element 40 from the thermal mass of the electrode 16. In the illustrated and preferred embodiment, the thermistor-containing cap 120 and associated barrier 142 are affixed by potting within the electrode well using cyanoacrylate FMD-13 (Loctite Corporation, Newington, Connecticut).

Therefore, the temperature condition sensed by the sensing element 40 within the cap 120 closely represents the actual tissue temperature condition that the cap 120 contacts.

EXAMPLE

The thermal sensitivity of a temperature sensing element enclosed in a thermally conductive carrier according to the invention (Sensor 1) was compared to the thermal sensitivity of a temperature sensing

element free of the carrier (Sensor 2).

Sensor 1 was carried within the well of an 8F 4 mm standard platinum/iridium radio frequency transmitting electrode. Sensor 1 comprised a 0.55

5   mm bead thermistor embedded in a glass bead, which in turn was embedded in an epoxy resin, which was encapsulated in a polyimide sheath. The entire encapsulated thermistor assembly was mounted by FMD-14 within a cap, as above described, made of

10 stainless steel 304 having a wall thickness of .005 inch. The exterior side walls of the cap were thermally isolated from the electrode by one layer of polyamide and one layer of polyester shrink tubing. The assembly was potted within the

15 electrode well using FMD-13. The distal tip of the cap was free of thermal insulating material and was flush with the distal tip of the electrode for contact with tissue.

Sensor 2 comprised a thermocouple potted with

20 solder in thermal conductive contact within an 8F/ 4 mm standard platinum/iridium radio frequency transmitting electrode.

The thermal sensitivity of each Sensor 1 and 2 was tested by placing the consolidated electrode and

25 sensor assembly into a water bath maintained at 20° C. A soldering wand maintained at a temperature of 60° C was placed into contact with each electrode beneath the surface of the water. This contact was maintained to achieve steady state conditions both

30 against the side of the electrode (the electrode being held horizontally) and at the distal tip of the electrode (the electrode being held vertically). The temperatures sensed by each Sensors 1 and 2 in both electrode orientations were recorded.

35   The following Table 3 summarizes the results:

TABLE 3

Comparison of the Thermal Sensitivity of a Temperature Sensor Carried Within a Thermal Conductive Surface to the Thermal Sensitivity of a Temperature Sensor Without a Thermal Conductive Surface

	VERTICAL POSITION	HORIZONTAL POSITION
SENSOR 1 (With Thermal Conductive Surface)	59° C	40°C
SENSOR 2 (Without Thermal Conductive Surface)	40°C	39°C

The above Table shows that Sensor 2 is not sensitive to the actual temperature of the 60° C heat source.   Regardless of its orientation, Sensor 2 continues to sense the 40° C temperature of the thermal mass of the electrode itself (the remainder of the heat energy of the source being dissipated by the surrounding water bath).

In contrast, Sensor 1 shows significant sensitivity with respect to its contact orientation with the 60° C heat source.   When held horizontally, out of direct contact with the heat source, Sensor 2, like Sensor 1, senses the 40° C temperature of the thermal mass of the electrode itself.   However, when held vertically, in direct contact with the heat source, Sensor 1 essentially senses the actual temperature of the heat source, and not the temperature of the electrode.   The cap encapsulating

Sensor 1, having a high intrinsic thermal conductivity of at least 1.0 W/m K, directly conducts heat from the source for sensing by Sensor 1. The thermal conducting cap creates an isothermal

5   condition about Sensor 1 close to the actual temperature of the source. Furthermore, the cap, being substantially isolated from thermal conductive contact with the electrode, retains this isothermal condition about Sensor 1, preventing its dissipation

10   by the thermal mass of the electrode.

In quantitative terms, the 59° C temperature sensed by Sensor 1 when in direct contact with the 60° C heat source, compared to the 40 C electrode temperature sensed when not in direct contact with

15   the source, accounts for 19 of the total 20 units of actual temperature difference between the heat source and the electrode. Thus, in quantitative terms, the presence of the thermal conducting cap in Sensor 1 establishes a 95% sensitivity to the

20   temperature of the heat source (i.e., which, in use, would be sensitivity to actual tissue temperature), and only a 5% sensitivity to the temperature of the electrode itself. This is compared to an essentially 100% sensitivity of Sensor 2 to the

25   temperature of the electrode. In the absence of the cap that embodies the invention, Sensor 2 is virtually insensitive to the actual temperature of the heat source (i.e., actual tissue temperature).

In the embodiment shown in Fig. 10, the cap 120

30   presents a blunt distal end 124 that projects from the end of the electrode 16, without actually penetrating it. As Fig. 10 shows, the endocardium is malleable enough to conform about the electrode 16 and the projecting cap 120.

35   In the alternative embodiment shown in Fig. 12,

the cap 120 presents a sharpened distal end 124 that actually penetrates the endocardium. By causing the cap 120 to actual penetrate the endocardium, better uniform tissue contact is achieved, both beneath the surface about the temperature sensing element 110 and at the surface along the electrode.

The temperature sensing element 110 can project into the tissue at any depth desired, depending upon the tissue morphology of the individual patient and the experience and judgment of the attending physician, provided, of course, that transmural penetration of the heart wall does not occur.

In the preferred embodiment (see Figs. 13 and 14), the temperature sensing element 110 is movable by the physician between a retracted position within the electrode well 118 (shown in Fig. 13) and an extended position outside the electrode well 118 (shown in Fig. 14) projecting into tissue. In Figs. 13 and 14, the temperature sensing element 110 is shown to have a blunt distal end 124, although a sensing element 110 having a sharpened distal end could also be used.

The movable nature of the temperature sensing element 110 shown in Figs. 13 and 14 provides added protection against bending or fracture of the element until the moment of use. The element 110 can be retained in a retracted, not exposed position during handling outside the body and while being deployed to the desired site within the body.

The movement of the temperature sensing element can be accomplished in various ways. In the embodiment shown in Figs. 13 and 14, a stylet 126 extends through the catheter body 22 within a braided protective sleeve 128 made of, for example, polyimide or stainless steel. The proximal end of

the stylet 126 is attached to a control knob 130 on the handle 20 (see Fig. 15A). The distal end of the stylet 126 is secured by adhesive, solder, crimping, or the like to the cap 120.

5   The thermistor wires 114 extend along the outside of the stylet 126 within the protective sleeve 128 (see Figs. 13 and 14). Another sleeve 132 of electrically insulating material, like heat shrink tubing made from Teflon® or polyester

10   material, surrounds the stylet 126 and wires 114 up to and around the junction between the cap 120 and the stylet 126. The sleeve 132 holds the wires 114 tightly against the stylet 126. The sleeve 132 also creates a smooth transition between the stylet 126

15   and cap 120, while further provides protection against electrical interference. A sleeve 136 of thermally insulating material, like polyimide, also preferably lines the interior of the well, to thermally insulate the cap 120 from the thermal mass

20   of the electrode 16.

        The stylet 126 can be manually or automatically advanced in various ways. In the illustrated embodiment, the stylet 126 includes helical lands 138 formed along its length (see Fig. 15A). The

25   lands 138 engage mating screw threads 142 within a stationary guide element 140 within the handle 20. Rotation of the control knob 130 by the physician rotates the stylet 126 within the guide element 140. Upon rotation in one direction, the helical lands

30   142 advance the stylet forward axially within the catheter body 22. Upon rotation in the opposite direction, the helical lands 142 move the stylet rearward axially within the catheter body 22. In this way, the sensing element 110 can be

35   incrementally moved in a controlled fashion between

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the retracted and extended positions.

In this arrangement (see Fig. 15B), the distal cap end 124 can itself be threaded with helical lands 146. Upon rotational advancement of the sensing element 110 by the stylet 126, the helical lands 146 engage tissue to better anchor the element 110 for temperature sensing. Alternatively (see Fig. 15C), the stylet 126 can be attached to a carrier 150 configured as a cork-screw. Like the helical lands 146, the cork-screw carrier 150 engages tissue during rotation as the stylet 126 is advanced forward by rotation. As Fig. 15C shows, the temperature sensing element 110 is secured in thermal conductive contact with the cork-screw carrier 150 near its distal tip.

In the illustrated and preferred embodiment, the distal cap end 124 and the distal tip of the electrode 16 are marked with a fluoroscopically dense material. In this way, the travel of the temperature sensing element 110 into the tissue can be monitored by fluoroscopy as the physician incrementally advances the element 110.

Alternatively, the stylet 126 can be advanced without rotation. In this arrangement (see Fig. 16), the proximal end of the stylet 126 includes a series of ribs 152, which successively make releasable, snap-fit engagement with detent 154 in the handle 20. As the physician moves the stylet 126 in a linear (push-pull) direction, the detent 154 captures the ribs 152 one at a time, releasing the captured rib 152 in response to further linear force. Like the rotating stylet 126 shown in Fig. 8, the linear (push-pull) stylet 126 shown in Fig. 16 permits controlled, incremental movement of the sensing element 110 into and out of tissue contact.

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In Figs. 10 to 16, the actively cooled electrodes 16 shown are of the metal types shown in Figs. 2A/B and 3A/B. It should be appreciated that a porous, actively cooled electrode body 66 like
5   that shown in Fig. 5 can also carry a temperature sensing element 110 of a fixed or movable kind.

In another alternative embodiment shown in Fig. 17A, the actively cooled electrode 16 (which is of an open system type, having outlet apertures 48 for
10   the cooling medium like that shown in Figs. 2A/B) includes a temperature sensing element 110 having multiple thermocouples designated 112(1), 112(2), and 112(3). The multiple thermocouples 112(1), 112(2), and 112(3) are arranged in a housing 156 in
15   a spaced-apart stacked relationship along the axis of the housing 156. The housing 156 can be fixed in an outwardly projecting position, as Figs. 10 and 12, or the housing 90 can be moved into an out of the projecting position in the manner of the stylet-
20   movable cap 120 previously described (as shown in Figs. 13 and 14).

In one embodiment (as Fig. 17A shows), the housing 156 comprises a body formed from a conventional potting compound, like silicon rubber,
25   RTV adhesive, polyurethane, or epoxy, having a thermal conductivity less than the tissue it contacts. In the illustrated environment, where the thermal conductivity of myocardium is about 0.43 W/m K, potting compounds like silicon rubber and
30   polyurethane material, for example, have thermal conductivities of, respectively, 0.13 W/m K and .026 W/m K. The relatively low thermal capacity of this material conditions the elements 112(1)/112(2)/112(3) to sense localized relative
35   changes in the tissue temperature gradient along

the length of the housing 156. The sensing of the
relative   temperature   gradient   permits   the
identification along the gradient of the   maximum
tissue temperature region for control purposes,
5   although the temperatures sensed by the elements
112(1)/112(2)/112(3) will not directly represent
actual tissue temperatures.

If a more direct correspondence between sensed
and actual tissue temperatures is required, the
10   housing 156 (see Fig. 17B) can include spaced bands
158(1), 158(2), and 158(3) of thermal conductive
material having thermal conductivity well above the
contacted tissue, of at least 1.0 W/m K, as already
described. The spaced bands 158(1), 158(2), 158(3)
15   establish localized regions of thermal conductive
contact between individual sensing element 112(1),
112(2), and 112(3) and tissue immediately adjacent
to the respective band. Thermal insulating material
160 substantially isolates the spaced bands 112(1),
20   112(2), and 112(3) from thermal conductive contact
with each another.   The thermally isolated bands
112(1), 112(2), and 112(3), each with a relatively
high thermal conductivity, more accurately obtain
the actual tissue temperature gradient along the
25   length of the housing 156, than when materials with
lower thermal conductivities are used.

In either embodiment, the multiple, axially
stacked thermocouples 112(1), 112(2), and 112(3)
allow the physician to obtain and monitor a profile
30   of temperate conditions at different depths beneath
the tissue surface. The physician can manually
select for ablation control purposes the one
thermocouple located in the hottest sub-surface
temperature region. Alternatively, an automated
35   control   mechanism   can   automatically   compare

temperatures from all thermocouples 112(1), 112(2),
and 112(3) and output the hottest sub-surface
temperature for temperature control purposes.

In the embodiment shown in Fig. 18, an array of
5   multiple, spaced-apart temperature sensing elements
(designated 110(1), 110(2), and 110(3)) project from
the actively cooled electrode 16 (which is of an
open system type, having outlet apertures 48 for the
cooling medium like that shown in Figs. 2A/B). Each
10   temperature sensing element 110(1), 110(2), and
110(3) is preferably contained within an isothermal
cap 120, as previously disclosed and contain a
single thermistor 112 (as Fig. 18 shows), or
multiple spaced-apart thermocouples (in the manner
15   shown in Figs. 17A/B). The array shown in Fig. 18
allows the physician to obtain and monitor a spatial
map of sub-surface temperature conditions about the
actively electrode 16. The physician can manually
select for ablation control purposes the one sensing
20   thermistor (or thermocouple, as the case may be)
located in the hottest sub-surface temperature
region. Alternatively, an automated control
mechanism can automatically compare temperatures
from all thermocouples 110(1), 110(2), and 110(3)
25   and output the hottest sub-surface temperature for
temperature control purposes. When the multiple-
sensor array shown in Fig. 18 is used, the proper
orientation of the electrode 16 generally
perpendicular to the tissue surface is less critical
30   than when single-sensor embodiments are used.

The embodiment shown in Fig. 20 includes a
motor-driven mechanism 162 for advancing the stylet
126. In this embodiment, the mechanism 162 includes
a feedback controller 164 electrically coupled to
35   the temperature sensing element 110. The feedback

controller 164 incrementally moves the stylet 126, while taking instantaneous measurements of temperature condition at each increment, to seek the sub-surface tissue region where the highest temperature conditions exist. The controller 164 outputs the sensed highest temperature while incrementally adjusting the position of the element 110, as necessary, to maintain it in the highest sub-surface temperature region.

Various control processes can be used to command movement of the stylet 126 to position the temperature sensing element 110 in the region of highest sub-surface tissue temperature. For example, proportional control principles, proportional integral derivative (PID) control principles, adaptive control, neural network, and fuzzy logic control principles can be used. Fig. 22 shows a representative control process 166 that the feedback controller 164 can use.

While incrementally moving the stylet 126, the process 166 inputs instantaneous tissue temperatures TT(t) sampled by the element 110 at a prescribed time interval Δt. Δt can vary according to the degree of accuracy and sensitivity required. For example, Δt can be 5 seconds.

The process 166 derives a temperature difference ΔTT between successive samples ($\Delta TT = TT(t) - TT(t-1)$). The process 166 employs prescribed course and fine differential temperature threshold values, respectively E_1 and E_2, to home in on the maximum tissue temperature. The differential threshold values can vary, again according to the accuracy and sensitivity required. For example, the course differential threshold value E_1 can be set to 5° C, and the fine differential threshold value E_2 can be

set to 1° C.

As long as ΔTT exceeds the course differential threshold E_1, the process 166 commands incremental advancement of the stylet 126, moving the element 110 deeper into tissue. When ΔTT equals or falls below E_1, the process 166 begins to command incremental retraction of the style 126 and element 110, while beginning to compare ΔTT to the fine differential threshold E_2. The process 166 continues to command incremental retraction of the stylet 126 as long as ΔTT ≤ E_1, until ΔTT drops below E_2, at which time the process 166 commands the stylet 126 to pause for the set time interval. The process 166 then repeats the above sequence, to seek and maintain the sensor 110 at the depth where the highest tissue temperature exists.

Preferably, the process 166 also sets upper absolute limits for advancing and retracting the stylet 126 and element 110 within tissue, so that the element 110 remains within a prescribed range of depths to avoid transmural penetration (if too deep) and loss of sub-surface tissue contact (if not deep enough). Preferably, the speed of incremental advancement or retraction should be faster than the speed of the thermal wave front in the tissue.

The system 148 shown in Fig. 19 is like the system 102 shown in Fig. 9A. As in the system 102, the cooled ablation electrode 16 carries three temperature sensing elements 104, 106, and 108, for sensing T1, T_{IN}, and T_{OUT}, respectively, as already described. Unlike system 102, in the system 148, the cooled ablation electrode 16 carries at least one additional temperature sensing element 110 for sensing actual tissue temperature.

In this arrangement, the master controller 98

receives from the physician, via the input device 100, a desired tissue temperature value TT_{SET}, a desired electrode temperature $T1_{SET}$, and a P_{MAX}. As earlier disclosed, the set temperature value TT_{SET} represents the desired hottest sub-surface tissue temperature that the physician wants to maintain at the ablation site, to thereby control the incidence of micro-explosions. TT_{SET} can comprise a fixed value or a set linear or nonlinear curve varying tissue temperature over time.

Likewise, the value $T1_{SET}$ represents a hottest temperature for the thermal mass of the cooled ablation electrode 16, which, as earlier stated, is believed to be between about 10° C and about 25° C.

The value P_{MAX} is the highest allowed power level, also based upon considerations already stated.

The master controller 98 periodically compares the sensed maximum tissue temperature T_{MAX} to TT_{SET}. Based upon this comparison, the master controller 98 derives a demand power output, taking into account P_{MAX}, while cooling to maintain $T1_{SET}$. The demand power output represents the magnitude of the radio frequency power that should be supplied to the electrode 16 to establish and maintain the desired maximum tissue temperature TT_{SET}.

Alternatively, the master controller 98 could maintain a fixed power level below P_{MAX} and adjust the cooling rate based upon sensed T_{MAX} to achieve TT_{SET}. As before described, the master controller 98 can control the cooling rate by commanding the temperature controller 92 to adjust the temperature of the cooling medium over time, or by commanding the pump controller 94 to adjust the flow rate of the cooling medium over time, or by commanding the

controllers 92 and 94 in tandem to reach the same result.

The manner in which the controller 98 derives the control commands can vary. For example, it can employ proportional control principles, proportional integral derivative (PID) control principles, adaptive control, neural network, and fuzzy logic control principles. Further details of these control principle are disclosed in copending U.S. Patent Application Serial No. 08/266,023, filed June 27, 1994, and entitled "Tissue Heating and Ablation Systems and Methods Using Time-Variable Set Point Temperature Curves for Monitoring and Control."

In a preferred implementation, the controller 98 sets a value for Å based upon the magnitude of the current demand power value, as set by the sensed tissue temperature condition T_{MAX}. The controller then controls the cooling rate to achieve the set value for Å. In this way, the controller maximizes the benefits of cooling the electrode at the demand power value.

The illustrated and preferred embodiments envision the use of micro-processor controlled components using digital processing to analyze information and generate feedback signals. It should be appreciated that other logic control circuits using micro-switches, AND/OR gates, invertors, and the like are equivalent to the micro-processor controlled components and techniques shown in the preferred embodiments.

Various features of the invention are set forth in the following claims.

WE CLAIM:

     1.   An apparatus for ablating body tissue comprising

     an electrode for contacting tissue at a tissue-electrode interface to transmit ablation energy at a determinable power level,

     an element to remove heat from the electrode at a determinable rate,

     a processing element to sample the power level at which the electrode transmits ablation energy and the temperature of the electrode, and to derive therefrom a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface.

     2.   An apparatus for ablating body tissue comprising

     an electrode for contacting tissue at a tissue-electrode interface to transmit ablation energy at a determinable power level,

     an element to remove heat from the electrode at a determinable rate,

     a processing element to sample the power level at which the electrode transmits ablation energy , the temperature of the electrode, and the rate at which heat is removed from the electrode, and to derive therefrom a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface.

     3.   An apparatus for ablating body tissue comprising

     an electrode for contacting tissue at a tissue-electrode interface to transmit ablation energy at a determinable power level,

     an element to remove heat from the electrode at a determinable rate, and

                    a processing element for retaining a
            function that correlates an observed relationship
10   among maximum tissue temperature below the tissue-
            electrode interface and a set of predetermined
            operating conditions; for sampling an actual
            operating condition; for comparing the actual
            operating condition to the function; and for
15   deriving from the comparison a predicted of the
            maximum tissue temperature.

                    4.   An apparatus according to claim 1 or
            2 or 3

                    wherein the processing element generates an
            output based upon the maximum tissue temperature
5   prediction.

                    5.   An apparatus according to claim 1 or
            2 or 3

                    wherein the processing element controls the
            power level of ablation energy transmitted by the
5   electrode based, at least in part, upon the maximum
            tissue temperature prediction.

                    6.   An apparatus according to claim 1 or
            2 or 3

                    wherein the processing element controls the
            rate at which heat is removed from the electrode
5   based, at least in part, upon the maximum tissue
            temperature prediction.

                    7.   An apparatus according to claim 1 or
            2 or 3

                    wherein the element that removes heat cools
            the electrode by directing a cooling medium into
5   thermal conductive contact with the electrode.

                    8.   An apparatus according to claim 7

                    wherein the processing element senses the
            rate at which heat is removed from the electrode by
            sensing temperature variations in the cooling medium

5   as a result of thermal conductive contact with the
     electrode.

          9.   An apparatus according to claim 8
          wherein the processing element controls the
     rate at which heat is removed from the electrode
     based, at least in part, upon the maximum tissue
5   temperature prediction.

          10. An apparatus according to claim 8
          wherein the heat removal rate is expressed
     as Å, where
          where:

$$\mathring{A} = c \times \Delta T \times RATE$$

5   c is the heat capacity of the
     cooling medium (in J/kg K),
                         ΔT is the temperature drop in the
     cooling medium due to thermal conductive contact
     with the electrode (in K), and
10   RATE is the mass flow rate of the
     cooling medium when coming into thermal conductive
     contact with the electrode (in kg/sec).

          11. An apparatus according to claim 10
          wherein the processing element controls the
     rate at which heat is removed from the electrode
     based, at least in part, upon the maximum tissue
5   temperature prediction.

          12. An apparatus according to claim 1 or
     2 or 3
                    wherein   the   processing   element
     includes a temperature sensing element in thermal
5   conductive   contact   with   the   electrode   to   sense
     temperature of the electrode.

          13. An apparatus according to claim 1 or

2 or 3

wherein the electrode transmits radio frequency energy.

14. An apparatus according to claim 1 or 2

wherein the processing element includes a neural network predictor.

15. An apparatus for supplying energy to an electrode for ablating tissue comprising

a generator adapted to be coupled to an electrode to supply energy to the electrode for
5   ablating tissue,

a cooling element to cool the electrode by directing a cooling medium into thermal conductive contact with the electrode,

a controller coupled to the generator to
10   supply power to the generator, the controller comprising

a first sensing element to measure temperature at the electrode,

a second sensing element to measure
15   power supplied to the generator, and

a processing element for sampling temperature sensed by the first sensing element and for sampling power sensed by the second sampling element and to derive therefrom a prediction of the
20   maximum tissue temperature condition occurring beneath the tissue-electrode interface and for generating a signal to control power supplied to the generator based, at least in part, upon the maximum tissue temperature prediction.

16. An apparatus for supplying energy to an electrode for ablating tissue comprising

a generator adapted to be coupled to an electrode to supply energy to the electrode for

5   ablating tissue,

        a cooling element to cool the electrode by
directing a cooling medium into thermal conductive
contact with the electrode,

        a controller coupled to the generator to
10   supply power to the generator, the controller
comprising

        a first sensing element to measure
temperature at the electrode,

        a second sensing element to measure
15   power supplied to the generator, and

        a processing element for sampling
temperature sensed by the first sensing element and
for sampling power sensed by the second sampling
element and to derive therefrom a prediction of the
20   maximum tissue temperature condition occurring
beneath the tissue-electrode interface and for
generating a signal to control the rate that the
cooling element cools the electrode based, at least
in part, upon the maximum tissue temperature
25   prediction.

        17.   An apparatus according to claim 16
        wherein the processing element generates a
signal to control power supplied to the generator
based, at least in part, upon the maximum tissue
5   temperature prediction.

        18.   An apparatus for supplying energy to
an electrode for ablating tissue comprising

        a generator adapted to be coupled to an
electrode to supply energy to the electrode for
5   ablating tissue,

        a cooling element to cool the electrode by
directing a cooling medium into thermal conductive
contact with the electrode,

        a controller coupled to the generator to

10   supply power to the generator, the controller
        comprising

                a first sensing element to measure
        temperature at the electrode,

                a second sensing element to measure
15   power supplied to the generator,

                a third sensing element to measure
        temperature variations in the cooling medium as a
        result of thermal conductive contact with the
        electrode, and

20   a processing element for sampling
        temperature sensed by the first sensing element, for
        sampling power sensed by the second sampling
        element, and for sampling temperature variations in
        the cooling medium sensed by the second sensing
25   element, and to derive therefrom a prediction of the
        maximum tissue temperature condition occurring
        beneath the tissue-electrode interface and for
        generating a signal to control power supplied to the
        generator based, at least in part, upon the maximum
30   tissue temperature prediction.

                19. An apparatus for supplying energy to
        an electrode for ablating tissue comprising

                a generator adapted to be coupled to an
        electrode to supply energy to the electrode for
5   ablating tissue,

                a cooling element to cool the electrode by
        directing a cooling medium into thermal conductive
        contact with the electrode,

                a controller coupled to the generator to
10   supply power to the generator, the controller
        comprising

                a first sensing element to measure
        temperature at the electrode,

                a second sensing element to measure

15   power supplied to the generator,

a third sensing element to measure temperature variations in the cooling medium as a result of thermal conductive contact with the electrode, and

20   a processing element for sampling temperature sensed by the first sensing element, for sampling power sensed by the second sampling element, and for sampling temperature variations in the cooling medium sensed by the second sensing

25   element, and to derive therefrom a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface and for generating a signal to control the rate at which the cooling element cools the electrode based, at least

30   in part, upon the maximum tissue temperature prediction.

20.   An apparatus according to claim 19

wherein the processing element generates a signal to control power supplied to the generator based, at least in part, upon the maximum

5   tissue temperature prediction.

21.   An apparatus according to claim 18 or

19

wherein the processing element derives a heat removal rate expressed as Å, where

$$\mathring{A}=c\times \Delta T\times RATE$$

5   where:

c is the heat capacity of the cooling medium (in J/kg K),

ΔT is the temperature drop in the
cooling medium due to thermal conductive contact
10   with the electrode (in K), as sensed by the third
sensing element, and

RATE is the mass flow rate of the
cooling medium when coming into thermal conductive
contact with the electrode (in kg/sec).

22.   An apparatus according to claim 18 or
19

wherein the generator supplies radio
frequency energy to the electrode.

23.   An apparatus according to claim 18 or
19

wherein   the   processing   element
includes a neural network predictor.

24.   An apparatus for supplying energy to
an electrode for ablating tissue comprising

a generator adapted to be coupled to
an electrode to supply energy to the electrode for
5   ablating tissue,

a   cooling   element   to   cool   the
electrode by directing a cooling medium into thermal
conductive contact with the electrode,

a controller coupled to the generator
10   to supply power to the generator, the controller
comprising

a   first   sensing   element   to
measure temperature at the electrode,

a   second   sensing   element   to
15   measure power supplied to the generator, and

a processing element for sampling
temperature sensed by the first sensing element and
for sampling power sensed by the second sampling
element; for comparing the sampled temperature and
20   sampled power to a function that correlates an

observed relationship among maximum tissue temperature below the tissue-electrode interface and a set of predetermined operating conditions including electrode temperature and power; and to

25   derive from the comparison a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface; and for generating a signal to control power supplied to the generator based, at least in part, upon the maximum

30   tissue temperature prediction.

25. An apparatus according to claim 24 wherein the element that removes heat cools the electrode by directing a cooling medium into thermal conductive contact with the electrode,

5   wherein the processing element also samples the rate at which the cooling medium is directed into thermal conductive contact with the electrode, and

wherein the predetermined operating

10   conditions that the function correlates includes the rate at which the cooling medium is directed into thermal conductive contact with the electrode.

26. An apparatus for supplying energy to an electrode for ablating tissue comprising

a generator adapted to be coupled to an electrode to supply energy to the electrode for

5   ablating tissue,

a cooling element to cool the electrode by directing a cooling medium into thermal conductive contact with the electrode,

a controller coupled to the generator

10   to supply power to the generator, the controller comprising

a first sensing element to measure temperature at the electrode,

15   a second sensing element to
measure power supplied to the generator, and

a processing element for sampling
temperature sensed by the first sensing element and
for sampling power sensed by the second sampling
element; for comparing the sampled temperature and
20   sampled power to a function that correlates an
observed relationship among maximum tissue
temperature below the tissue-electrode interface and
a set of predetermined operating conditions
including electrode temperature and power; and to
25   derive from the comparison a prediction of the
maximum tissue temperature condition occurring
beneath the tissue-electrode interface; and for
generating a signal to control the rate at which the
electrode is cooled based, at least in part, upon
30   the maximum tissue temperature prediction.

27. An apparatus according to claim 26
wherein the element that removes heat
cools the electrode by directing a cooling medium
into thermal conductive contact with the electrode,
5   wherein the processing element also
samples the rate at which the cooling medium is
directed into thermal conductive contact with the
electrode, and

wherein the predetermined operating
10   conditions that the function correlates includes the
rate at which the cooling medium is directed into
thermal conductive contact with the electrode.

28. An apparatus according to claim 27
wherein the processing element
controls the rate at which the electrode is cooled
by controlling the rate that heat is removed from
5   the electrode derived by sensing temperature
variations in the cooling medium as a result of

thermal conductive contact with the electrode.

29. An apparatus according to claim 27 wherein the processing element derives a heat removal rate expressed as Å, where

$$\mathring{A} = c \times \Delta T \times RATE$$

where:

5   c is the heat capacity of the cooling medium (in J/kg K),

ΔT is the temperature drop in the cooling medium due to thermal conductive contact with the electrode (in K), and

10   RATE is the mass flow rate of the cooling medium when coming into thermal conductive contact with the electrode (in kg/sec).

30. A method for ablating body tissue comprising the steps of

supplying ablation energy to an electrode,

5   conducting heat from the electrode,

sensing temperature at the electrode,

sensing power transmitted by the electrode, and

deriving from the sensed temperature

10   and sensed power a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface.

31. A method for ablating body tissue comprising the steps of

supplying ablation energy to an electrode,

5   conducting heat from the electrode,
             sensing temperature at the electrode,
             sensing power transmitted by the
electrode,
             sensing the rate at which heat is
10   conducted from the electrode, and
             deriving from the sensed temperature,
sensed power, and sensed heat conduction rate a
prediction of the maximum tissue temperature
condition occurring beneath the tissue-electrode
15   interface.

             32. A method for ablating body tissue
comprising the steps of
             supplying ablation energy to an
electrode,
5   conducting heat from the electrode,
             sensing temperature at the electrode,
             sensing power transmitted by the
electrode, and
             comparing the sensed temperature and
10   sensed power to a function that correlates an
observed relationship among maximum tissue
temperature below the tissue-electrode interface and
a set of predetermined operating conditions
including electrode temperature and power, and
15   deriving from the comparison a
prediction of the maximum tissue temperature
condition occurring beneath the tissue-electrode
interface.

             33. A method according to claim 30 or 31
or 32
             and further including the step of
generating a signal to control the supply of
5   ablation energy based, at least in part, upon the
predicted maximum tissue temperature condition.

34. A method according to claim 30 or 31 or 32

and further including the step of controlling the rate at which heat is conducted from the electrode based, at least in part, upon the predicted maximum tissue temperature condition.

35. A method according to claim 34

wherein the step of conducting heat removes heat by directing a cooling medium into thermal conductive contact with the electrode.

36. A method according to claim 35

wherein the rate at which heat is removed from the electrode is sensed based upon temperature variations in the cooling medium as a result of thermal conductive contact with the electrode.

37. A method according to claim 35

wherein the rate at which heat is conducted from the electrode is derived from a heat removal rate expressed as Å, where

$$\dot{A} = c \times \Delta T \times RATE$$

where:

c is the heat capacity of the cooling medium (in J/kg K),

ΔT is the temperature drop in the cooling medium due to thermal conductive contact with the electrode (in K), as sensed by the second sensing element, and

RATE is the mass flow rate of the

cooling medium when coming into thermal conductive contact with the electrode (in kg/sec).

38. A method according to claim 30 or 31 or 32

wherein the step of sensing temperature at the electrode uses a temperature sensing element in thermal conductive contact with the electrode to sense temperature of the electrode.

39. A method according to claim 30 or 31 or 32

wherein radio frequency energy is supplied to the electrode.

40. A method according to claim 30 or 31

wherein the step of deriving the predicted maximum tissue temperature uses a neural network predictor.

41. A method according to claim 32

wherein the step of conducting heat removes heat by directing a cooling medium into thermal conductive contact with the electrode,

and further including the step of sensing the flow rate at which the cooling medium is directed into thermal conductive contact with the electrode,

wherein the set of predetermined operating conditions of the function includes flow rate of the cooling media and the comparison step also compares the sensed flow rate to the function.
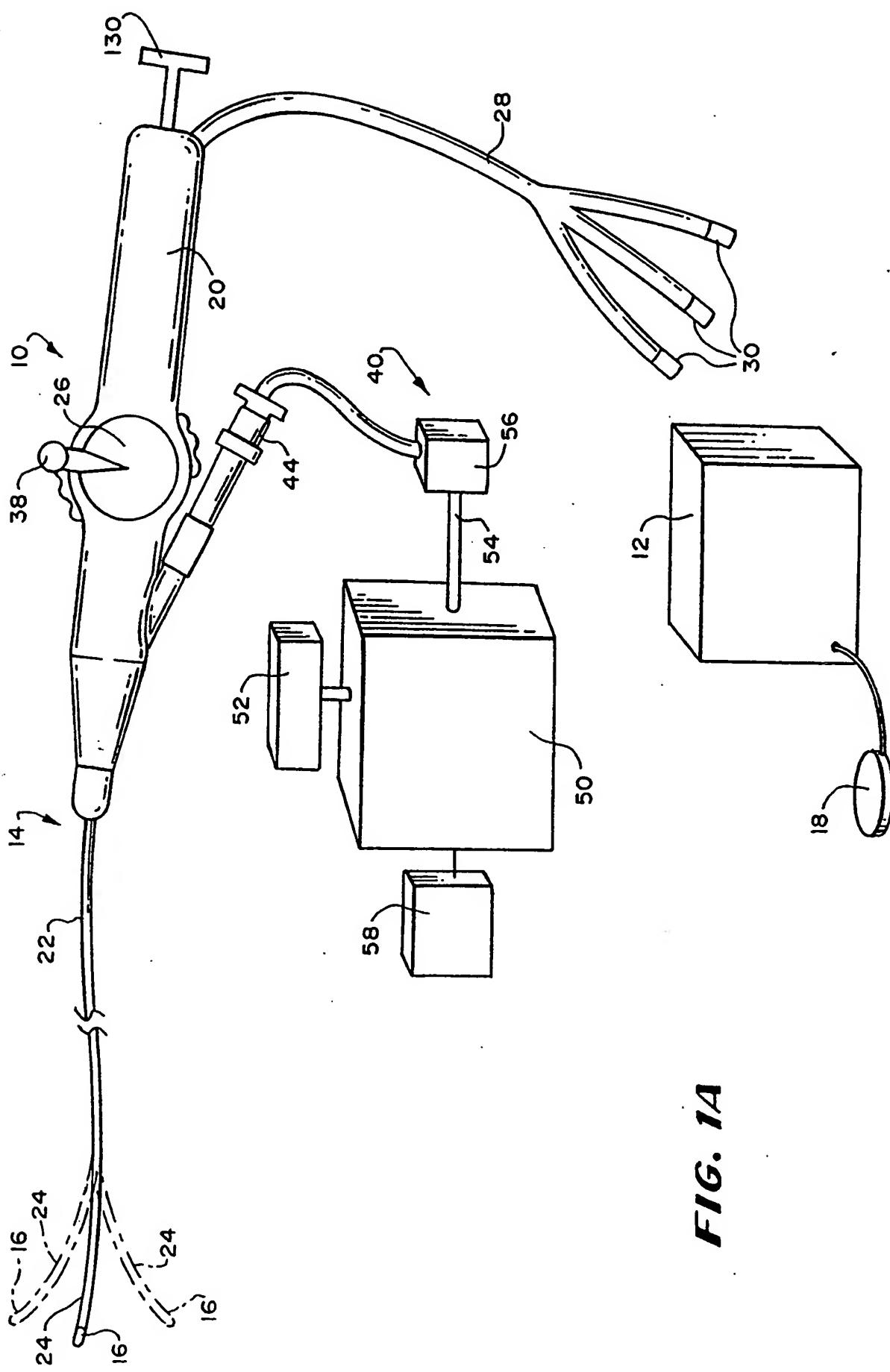
FIG. 1A

FIG. 1B
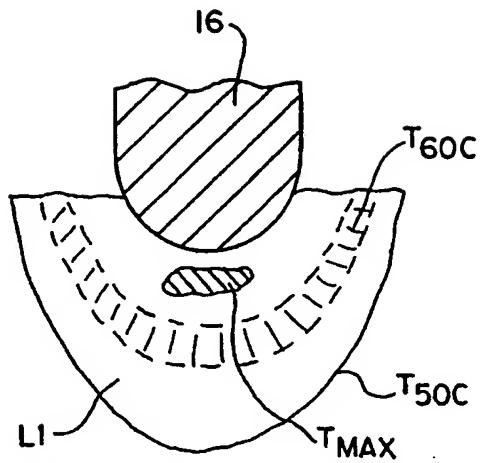
FIG. 1C
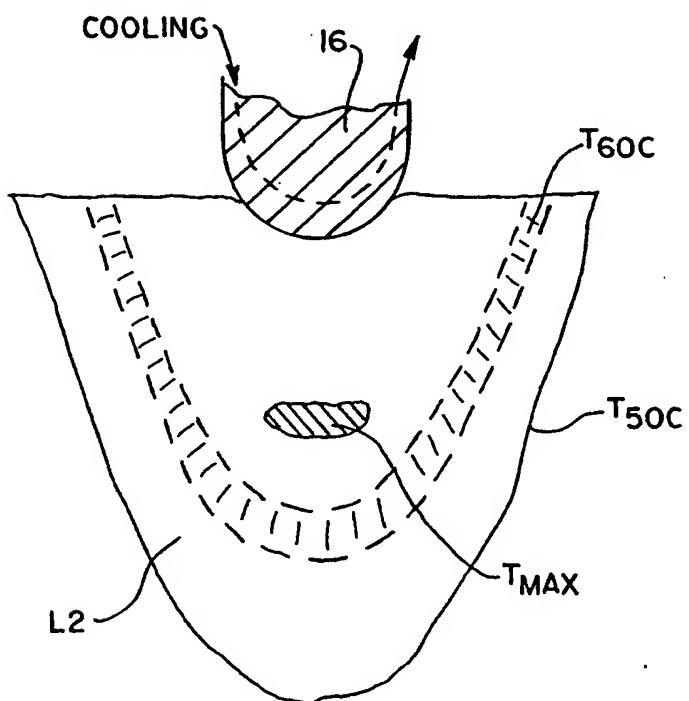
FIG. 1D
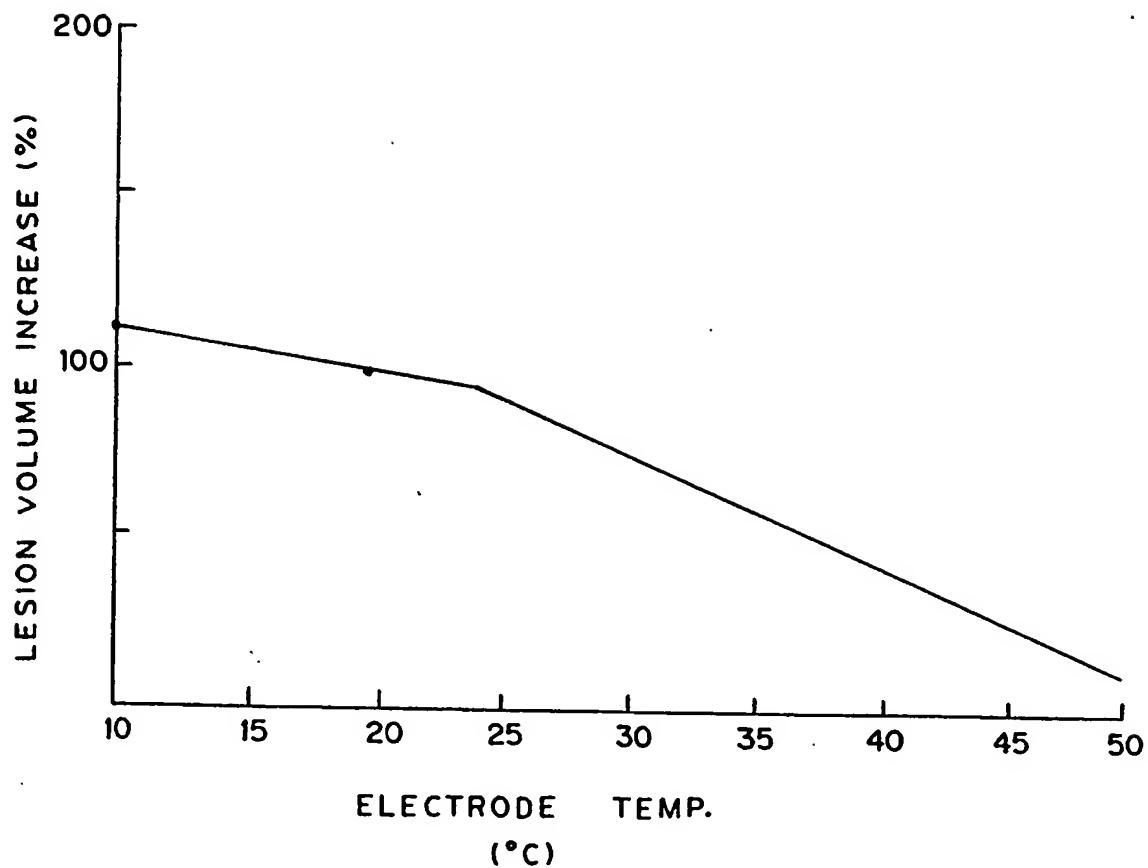
LESION VOLUME INCREASE

VS.

ELECTRODE TEMPERATURE

(MAXIMUM TISSUE TEMPERATURE
AT 94°C)

FIG. 2A

12

52

40

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54

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32

34

42

22

36

FIG. 2B

16

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46

16

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48

48

FIG. 3A

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50

54

56

12

32

60

64

64

3B

3B

16

FIG. 3B

16

64

60

62

62

64

64

62

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64

62

FIG. 4

64A

A

64B

B

16

62

60

62

64C

B

6/20

FIG. 6

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22

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FIG. 5

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FIG. 7

FIG. 8

FIG. 9A

FIG. 9B

FIG. 10

FIG. 11

FIG. 12

FIG. 13

FIG. 14
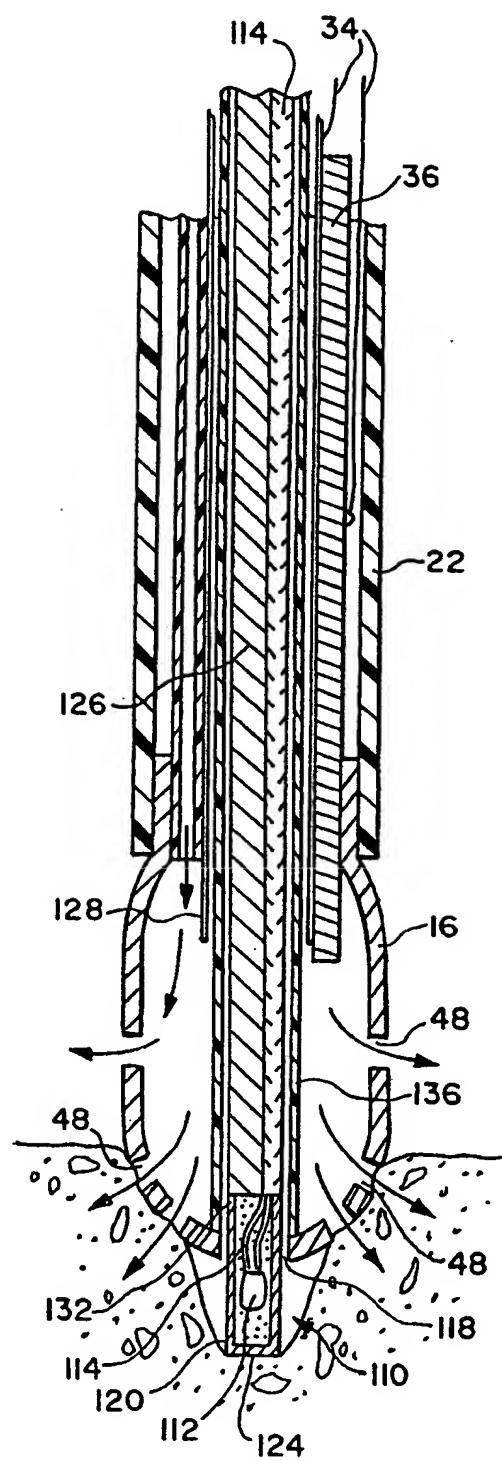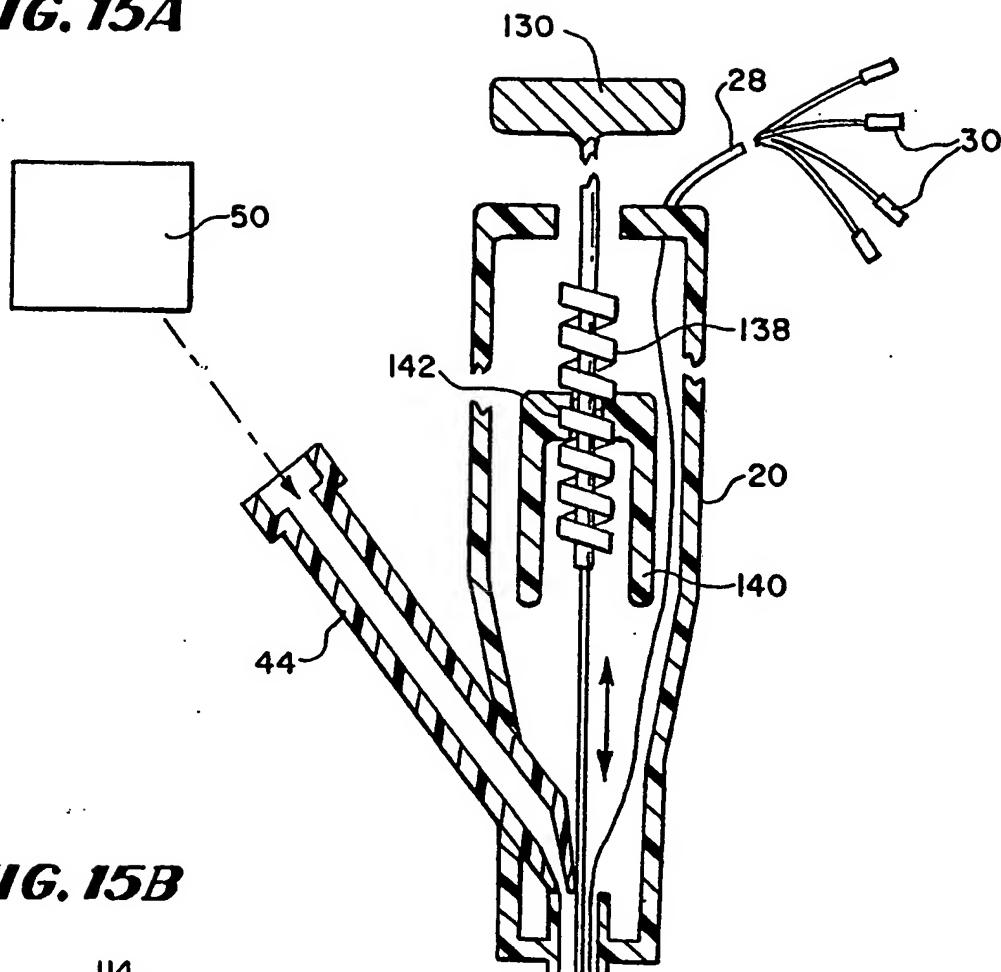
FIG. 15A

FIG. 15B

FIG. 15C

14/20

FIG. 16

FIG. 17A

FIG. 17B

FIG. 18

FIG. 19

FIG. 20

18/20

162

ADVANCE SENSOR

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138

142

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140

44

22

SEEK
T_MAX

126

164

16

110
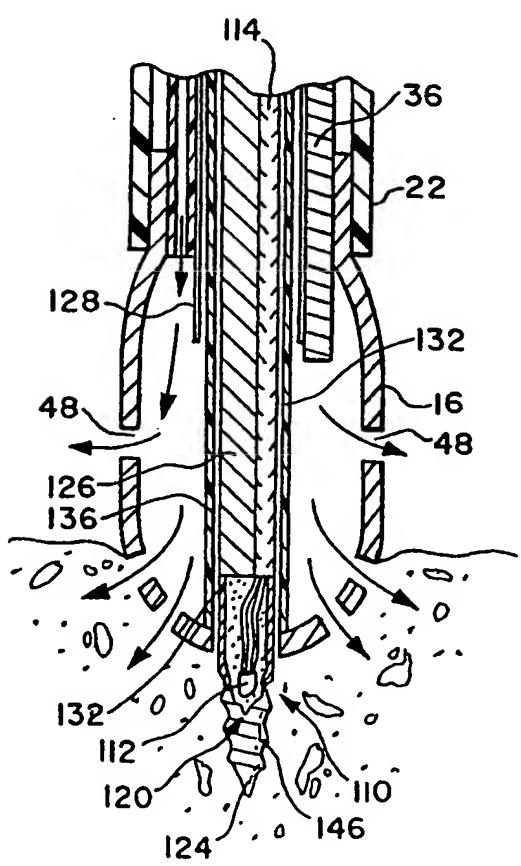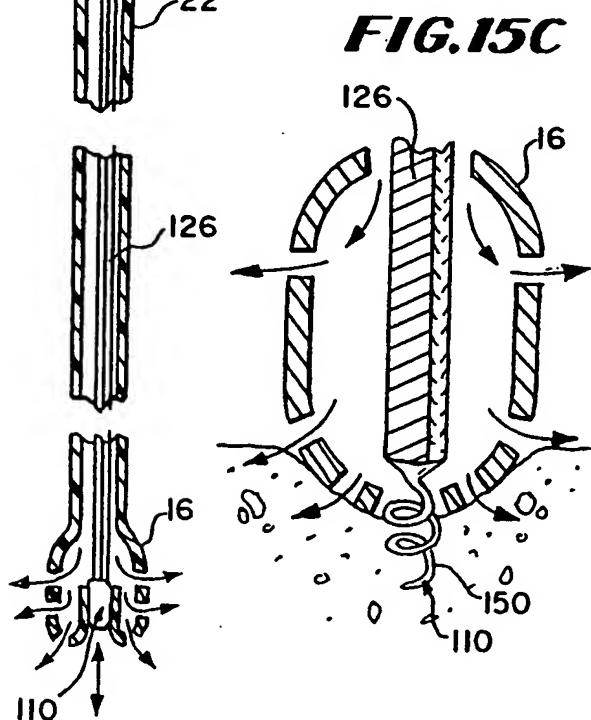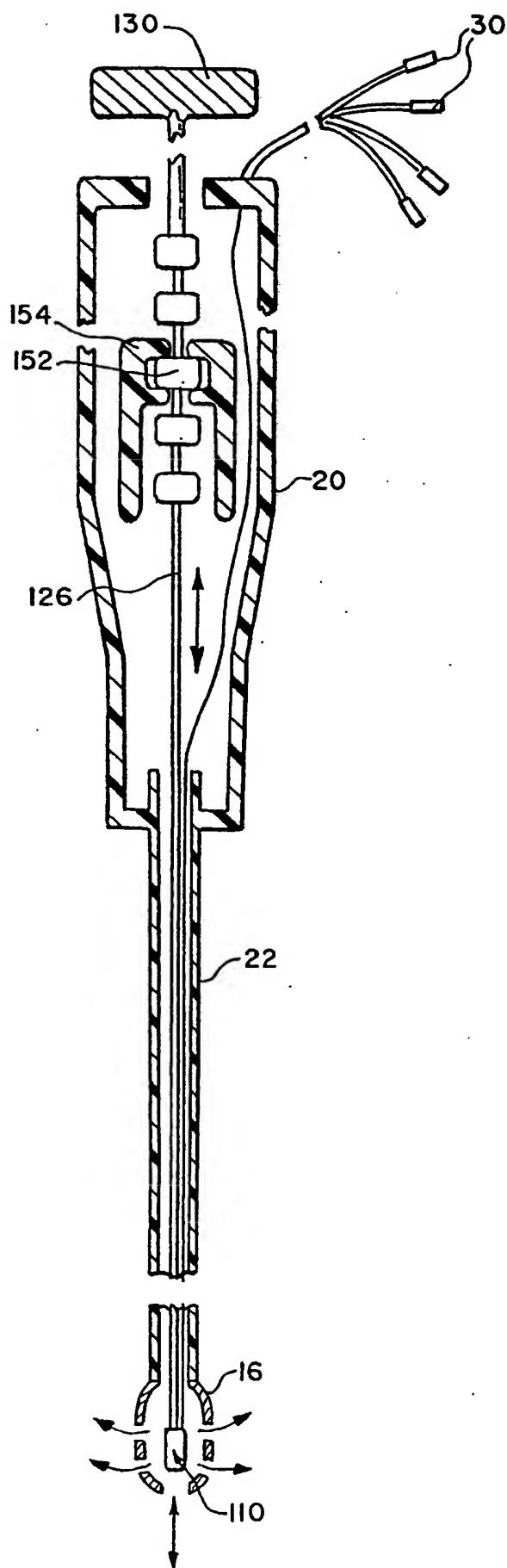
SUBSTITUTE SHEET (RULE 26)

FIG. 21
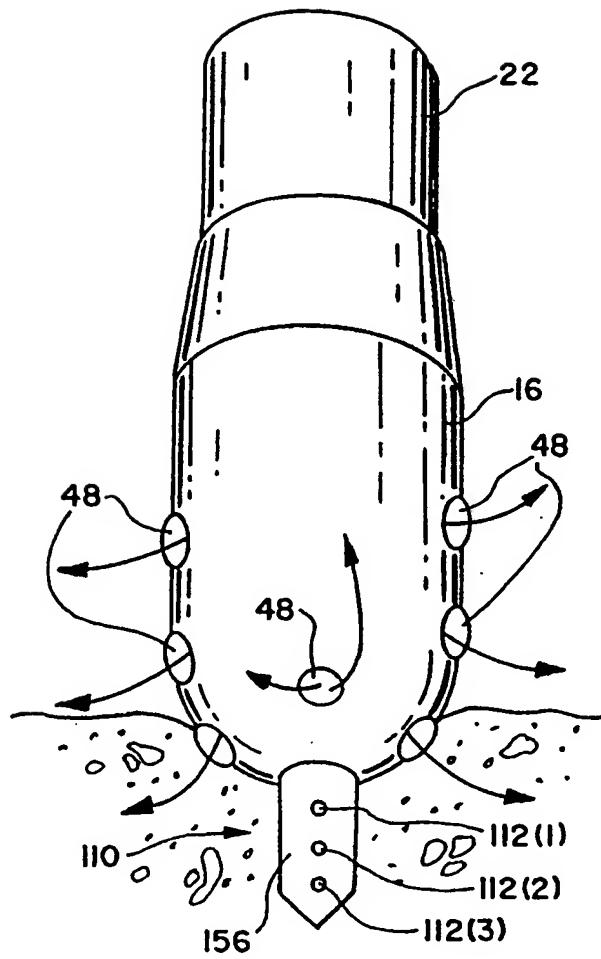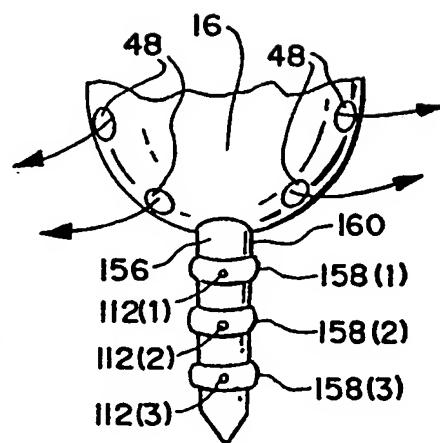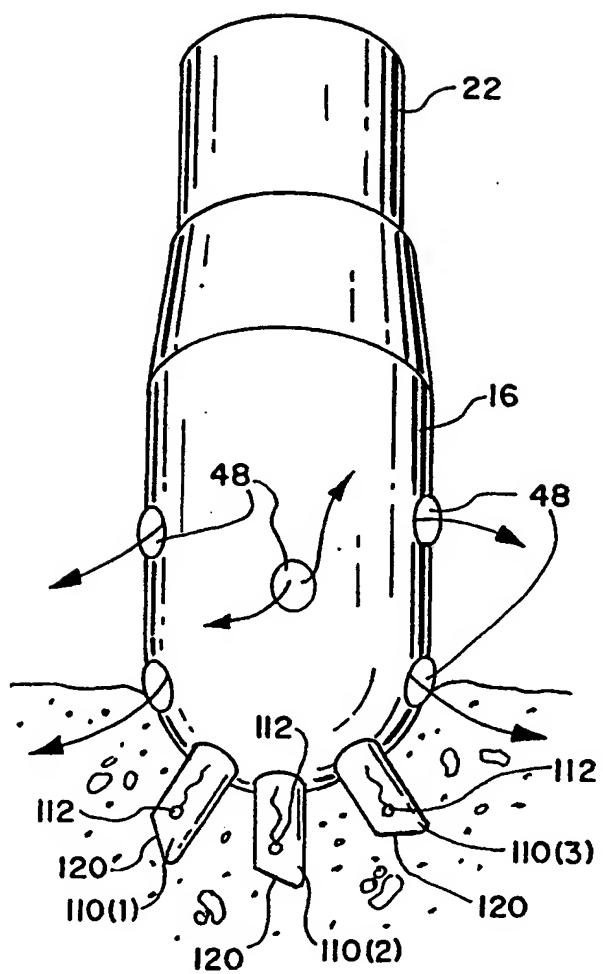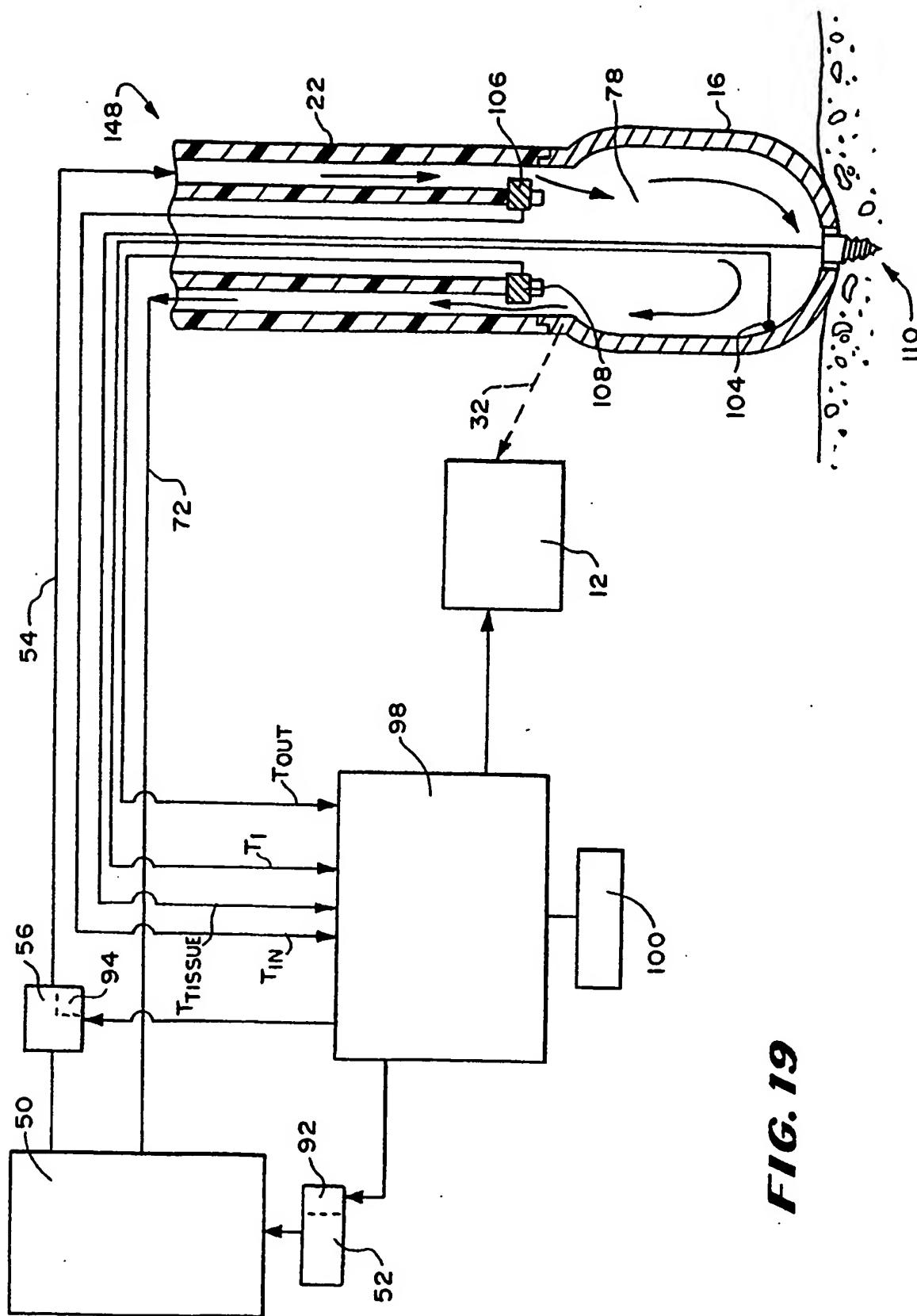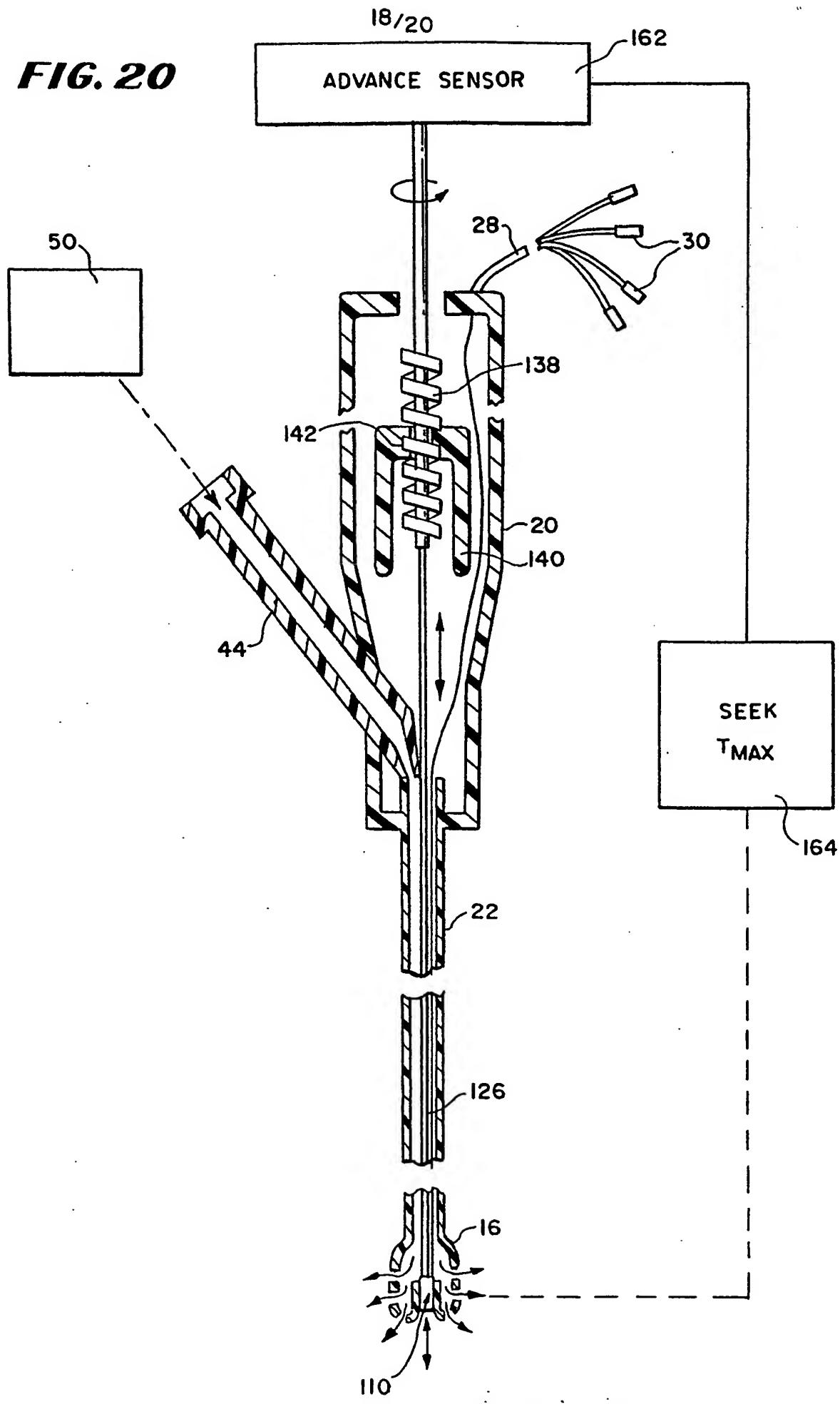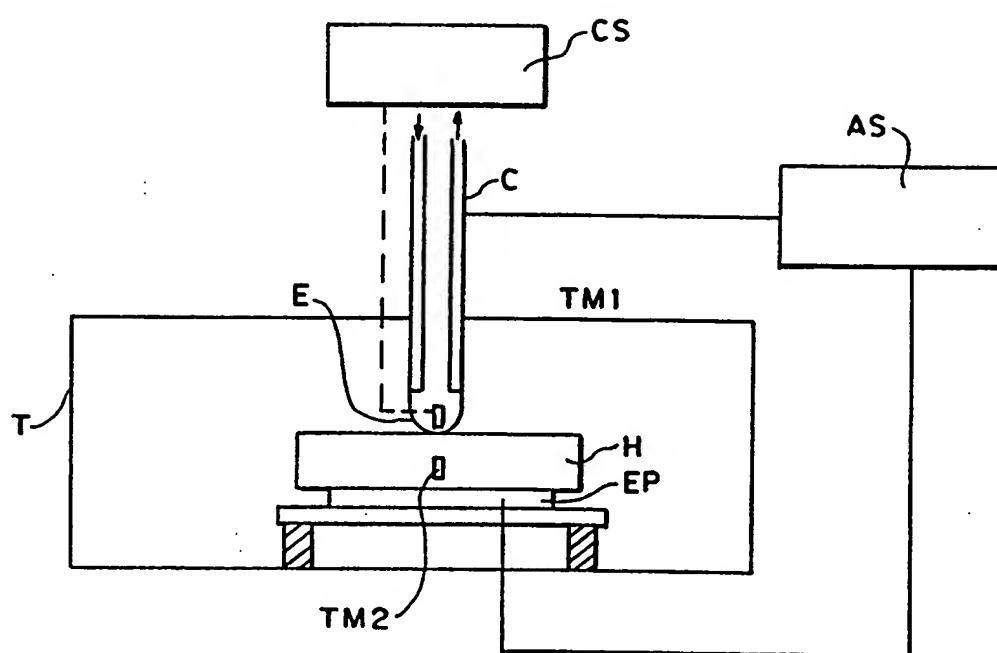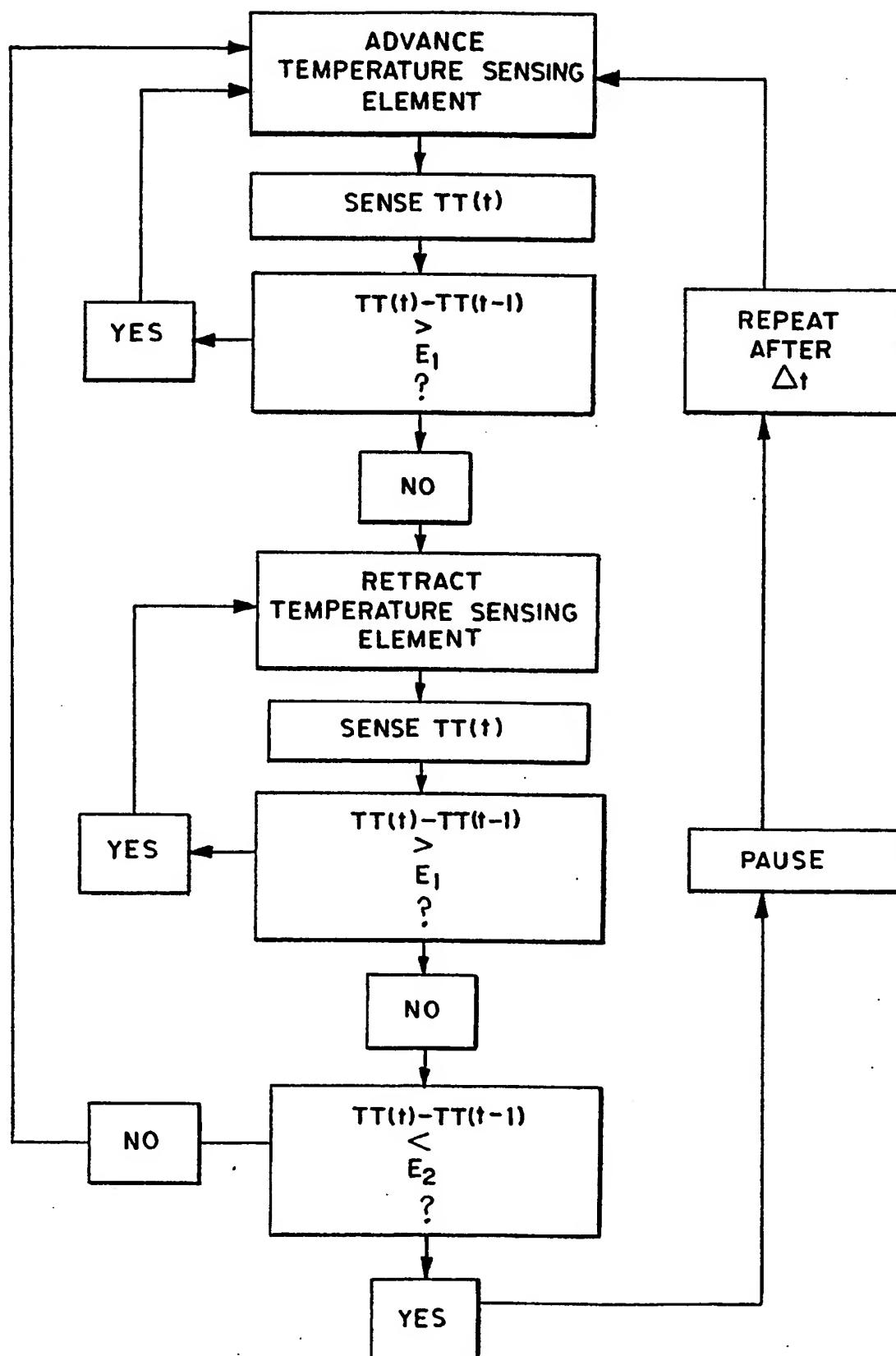
FIG.22

166

ADVANCE
TEMPERATURE SENSING
ELEMENT

SENSE TT(t)

$$TT(t)-TT(t-1) > E_1 ?$$

YES

NO

RETRACT
TEMPERATURE SENSING
ELEMENT

SENSE TT(t)

$$TT(t)-TT(t-1) > E_1 ?$$

YES

NO

$$TT(t)-TT(t-1) < E_2 ?$$

NO

YES

REPEAT
AFTER
$\triangle t$

PAUSE

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 17/39
US CL :606/42

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/21, 22; 606/27-31, 41, 42, 45-50; 607/96, 98, 100-102, 115, 116, 122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,330,518 (NEILSON ET AL.) 19 July 1994, see whole document.	1-9, 12, 13, 15-20, 22, 24-28, 30-36, 38, 39, 41 ---------------- 10, 11, 14, 21, 23, 29, 37, 40
X	US, A. 5,334,193 (NARDELLA) 02 August 1994, see whole document.	1-7, 12, 13
A, P	US, A, 5,423,811 (IMRAN ET AL.) 13 June 1995, see whole document.	1-41

☐ Further documents are listed in the continuation of Box C.   ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance		
"E"	earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 JUNE 1996	03 JUL 1996

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	MICHAEL PEFFLEY
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